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PROPOSED REGULATIONS GOVERNING REIMBURSEMENT UNDER THE MEDICARE END-STAGE RENAL DISEASE PROGRAM

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT

OF THE

COMMITTEE ON WAYS AND MEANS

HOUSE OF REPRESENTATIVES

NINETY-SEVENTH CONGRESS

SECOND SESSION

APRIL 22, 1982

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PROPOSED REGULATIONS GOVERNING REIMBURSEMENT UNDER THE MEDICARE END-STAGE RENAL DISEASE PROGRAM

THURSDAY, APRIL 22, 1982

House of Representatives,
Committee on Ways and Means,
Subcommittee on Oversight,
Washington, D.C.

The subcommittee met at 10:10 a.m., pursuant to notice, in room B-318, Rayburn House Office Building, Hon. Charles Rangel (chairman of the subcommittee) presiding.

[The press release follows:]

[Press Release of Thursday, Apr. 8, 1982]

HON. CHARLES B. RANGEL, DEMOCRAT OF NEW YORK, CHAIRMAN, SUBCOMMITTEE ON OVERSIGHT, COMMITTEE ON WAYS AND MEANS, U.S. HOUSE OF REPRESENTATIVES, ANNOUNCES A HEARING ON THE PROPOSED REGULATIONS GOVERNING REIMBURSEMENT UNDER THE MEDICARE END-STAGE RENAL DISEASE PROGRAM

The Honorable Charles B. Rangel, Chairman of the Ways and Means Committee's Subcommittee on Oversight, announced today that the Subcommittee will hold a hearing on the proposed end-stage renal disease regulations which have been the subject of intensive scrutiny by both the Oversight and Health Subcommittees. The hearing will be held on April 22, 1982, in Room 1100 Longworth House Office Building, beginning at 10 a.m.

Under legislation enacted in 1978 and subsequently amended in 1981, the Secretary of Health and Human Services is required to develop and implement an incentive reimbursement system to assure the cost-effective delivery of renal dialysis services and to encourage use of home dialysis by suitable candidates. The statute requires the Secretary to establish prospectively determined rates on the basis of composite weighted formulas for hospital-based and for independent facilities that take into account the proportions of patients dialyzing in facilities and at home, as well as the relative costs of providing services in each setting.

On February 12, 1982, the proposed regulations setting forth the new payment system and rate-setting methodologies were issued. However, these proposed regulations have become the subject of widespread controversy and criticism; serious questions have been raised about their objectivity, equity and potential effect on the continuing stability of the program. In announcing the hearing, Chairman Rangel indicated that there is considerable Congressional concern as well. "We do not believe," he said, "that such widespread concern should be taken lightly. The reservations raised about the objectivity of the rate-setting methodology, the adequacy of the data base, the absence of a reasonable transition period and exception process, and several other provisions warrant serious and thorough reevaluation of the regulations."

Due to time restrictions, the hearing will be limited to testimony from the Administration and invited witnesses representing providers of renal dialysis and transplant services, administrators of facilities, physicians and patients. The Subcommittee will also be receiving a detailed report from the Secretary on the voluminous correspondence received by the Department during the prescribed comment period. Nonetheless, the Subcommittee welcomes written statements for inclusion in the printed record from any interested person or organization. Such statements will be given the same full consideration afforded to direct personal testimony.

Although this hearing will focus exclusively on the problems raised by the proposed regulations, the Chairman stated that the Subcommittee will be exploring a variety of other issues in the management and operation of the ESRD Program at public hearings to be announced at a later date.

Procedure to be followed for submitting written statements: Interested individuals and organizations may submit written statements through the close of business, Friday, April 30, 1982. Five copies of such statements should be submitted to John J. Salmon, Chief Counsel, Committee on Ways and Means, 1102 Longworth House Office Building, Washington, D.C. 20515.

Chairman RANGEL. The Oversight Subcommittee of the Committee on Ways and Means will open its hearings on the proposed regulations governing reimbursement under medicare end-stage renal disease program.

The purpose of our hearings today is to examine the proposed end-stage renal disease regulations that concern many providers, patients, and Members of Congress who have expressed deep concern about these proposed regulations and the possible implications for patient care and the availability of services if the regulations are promulgated in their present form.

I want to make it abundantly clear that we are not here today simply to engage in another political legislative exercise. The issue goes far beyond that stage. The end stage is too important to the very lives of the people involved to be handled casually or to make changes without being sure of what effects those changes will have and why sufficient attention has not been given to all the details involved in this program that directly concerns the very lives of people involved in it.

We want at this hearing, therefore, to assess the problems in regulations as seen by the patients, their physicians and providers. What modifications they believe can and should be made to produce a more acceptable and workable reimbursement system, and whether the Department recognizes these views and can accommodate them.

I want to urge the witnesses to recognize that their complete statements will be placed into the record. The concern of this committee is for witnesses to direct themselves to these specific questions: The equity of the reimbursement and the protection of the patient.

In this same spirit, I hope the Department's representatives will respond to the witnesses concerns and recommendations. I expect that some of the testimony they will be hearing today is not new to them. The debate on this issue has been going on for the last 2 months. But while critics of the regulations have been vocal—particularly in the case of patients who have gone through a traumatic experience—the Department has not given any indication of its current position. In my view, the Department's participation in the discussion is now sorely needed.

I have some political problems as many of the patients have been allowed to believe that their clinics and providers will be going out of business. This has caused absolute panic for kidney disease patients throughout the country. Whether this was handled professionally and properly or not, I do not know.

The issue today is whether there has been any real reason for this type of concern, and the involvement of the Department is most necessary and that is the reason we are having these hearings.

Congressman Andy Jacobs and I have sent a letter to Secretary Schweiker on March 30, outlining in some detail our concerns about these proposed regulations and directing his staff to work with subcommittee staff to see if we can address these concerns. I do hope that the Department is prepared to discuss and respond to our request. If ever an issue cried out for nonpartisan effort or cooperative effort to achieve a viable solution, surely this issue of a sound reimbursement system for ESRD program is it.

One final point before we begin the testimony and hear from Congressman Pickle. We are all engaged in a common effort to find ways to make Federal programs more cost-effective and more responsive to human needs. I think it needs to be clearly understood by all parties that this process involves changes, and possibly sacrifices will have to be made and accepted by everyone.

But in accomplishing this objective, we don't want to lose sight of the fact that lives are at stake here, and however vital it is to bring about cost-effectiveness, we dare not do so at the price of condemning renal patients to a poorer quality of care or restricting access to care, or making decisions when we don't know what the end results will be.

We have to make certain that we seek a balanced approach, one that stimulates more cost-effective delivery of services, that assures patients and provider awareness of the costs involved in maintaining the program, and also gives assurance that these services will be provided to all those who need them.

It seems to me that while I have some concern about the method by which the providers brought their concern to the public, and especially to the patients, I do believe that the administration should have shared with Members of Congress who enacted this legislation. They should realize that legislative intent does not mean proposing regulations that would cause services to be reduced. This is the responsibility of the Congress. If there are any changes in programs, these changes should be brought to the Congress.

We had hoped and still hope that we can discuss the changes in the program that will not involve legislation, but the purpose of this hearing today is to give assurances to patients and providers that their two branches of Government, the executive and legislative branches, will be exercising their constitutional authority.

Mr. Pickle.

Mr. PICKLE. I commend you, Mr. Chairman, for holding these hearings. This is an extremely important issue for those engaged in this particular work, and extremely important also to the people who suffer from end-stage renal disease. I will be with you off and on during the day. I must go and have a conference with the chairman.

During the day, one of the panelists will be Dr. Jack Moncrief from Austin, Tex., who has given national leadership in the treatment approach of this disease. I am pleased he is here, and I look forward to participating in this hearing.

Chairman RANGEL. Thank you very much, Mr. Pickle.

We will first hear from a panel with John Newmann, president of the National Association of Patients on Hemodialysis and Transplantation, Inc., accompanied by Margaret Diener. It is good to see both of you again.

Dr. Richard M. Freeman, president of the National Kidney Foundation, Department of Medicine, University Hospital, Iowa City.

Calvin Bland, executive director, St. Christopher's Hospital for Children in Philadelphia.

Mr. DUNCAN. John Newmann has been delayed, and he will be summarizing his statement.

STATEMENT OF MARGARET DIENER, EXECUTIVE DIRECTOR, NATIONAL ASSOCIATION OF PATIENTS ON HEMODIALYSIS AND TRANSPLANTATION, INC., ACCOMPANIED BY JOHN NEWMANN, PRESIDENT

Ms. DIENER. Congressman Rangel, and Congressman Pickle, I want to thank you for the opportunity to appear here today on behalf of the National Association of Patients on Hemodialysis and Transplantation. Your concern and interest in protecting patients is deeply appreciated by the association and the patients.

I am Margaret Diener, the executive director of the association.

NAPHT has always had as its foremost concern that all people needing treatment for irreversible kidney failure have access to that care. The major objective of Public Law 92-603 is that that care be available and be of the highest possible medical quality.

The proposed rules published in the February 12, 1982, Federal Register are particularly troublesome because of their potential impact on those two issues. Our specific comments are addressed to our concerns about access to high quality care.

We recognize that there is need for some changes in the end-stage renal disease program. However, the proposed rules put too many patients at too great a risk. According to the analysis by the Health Care Financing Administration, and I quote from the Federal Register,

> These rates would result in reimbursing 46 percent of all hospital based facilities and 28 percent of all independent facilities at rate per treatment below their current costs for in-facility dialysis.

This analysis does not indicate how many of these facilities have a sufficient percentage of patients on home dialysis to offset the losses incurred by in-center patients, nor does it indicate where other facilities are available to handle patients who might at risk in those facilities.

It is the fate of those patients in those facilities, both in-center and at-home patients, that is of very great concern to us because we believe the proposed rule has so much potential damaging effect on both access and quality.

We would like to see that the proposed rule be withdrawn and rewritten. At a minimum, it requires very major revisions. We have submitted for the record our comments to the Secretary on the proposed rule, which outline some of specific things. I would like to highlight several issues.

One is the concern among patients that the composite nature of the regulations will have potential for abuse. Currently, the target rate reimbursement program has a number of specific service requirements. We would like to see it mandated that those service requirements be maintained under the current composite rate.

Second, we are concerned about units which cannot send a significant number of patients home for medical, economic, or environmental reasons. We, along with a number of other people who have appeared at hearings here before, recognize that home dialysis has been underutilized in the past. We are suggesting that the criteria for an exception for a typical patient mix specifically include an exception to the composite rate for those units who are not able to send many patients home.

The third thing is, we think it is irresponsible to implement a new regulation with this major impact on the day that it is published in the Federal Register in final form. We would like to see a 30-day from the time of publication to the time of implementation, also some kind of phase-in schedule of at least 9 months to give facilities the time to train patients, send them home, and develop all of the economies that have been suggested.

We think there are some things that could be done even without the regulation to begin sending saving money because we recognize the legitimacy of the concern. First, we think nonproductive expenditures should be eliminated by better management, and possibly through single or several intermediaries and by prosecution of fraud, double billing, billing for no shows is not acceptable.

Second, we recognize there are currently some facilities which have very high reimbursement rates which were apparently never audited prior to receiving exceptions. We think the Department should begin auditing the highest cost facilities now in dealing with those issues, while they develop an equitable system.

There are several areas we think may require legislative intervention, and I would like to briefly mention those.

As part of our analysis of the regulation, we surveyed the leadership of our organization, both our board of directors and our chapters, and one thing became very clear through that survey. Patients saw incentives for facilities and incentives for physicians, they did not see incentives for patients. They want to choose their physician, their facility, and their mode of treatment, and they would like to see some of the incentives given to them. There are a number of ways that that could be done.

Second, I think there is tremendous concern about the quality of care. We know that a high level of funding does not guarantee good care, but the opposite is true. In the absence of sufficient funding, it is impossible to get good care. We would like to see a number of things done to deal with that issue. Again, there are some specifics in the statement.

In summary, NAPHT believes that the proposed rule, if implemented as currently written, creates an unacceptable risk of substantial disruption in the renal care system, with potentially life threatening results. We again urge the administration and Congress to carefully examine and revise the proposal so that all patients needing care, receive that care.

We at the association are willing and eager to work with other groups, professional, provider, administrative, and legislative, to assure that access to high quality care is guaranteed to all. We would be happy to answer any questions.

[The prepared statement follows:]

STATEMENT OF JOHN NEWMANN, PH. D., M.P.H., PRESIDENT, NATIONAL ASSOCIATION OF PATIENTS ON HEMODIALYSIS AND TRANSPLANTATION, INC.

Mr. Chairman and Members of the Committee, I wish to thank you for the opportunity to appear here today on behalf of the National Association of Patients on Hemodialysis and Transplantation, more commonly known as NAPHT. I serve as President of this Association, and I am a home dialysis consumer of ten years. Also appearing with me today is the Executive Director of the Association, Margaret Diener.

NAPHT's membership includes over 10,000 kidney patients from every state as well as from the U.S. territories. We currently have 33 chapters in 18 states. Kidney patients generally and NAPHT members in particular have become quite knowledgeable about their disease.

Before addressing the specific issues being reviewed today, I would like to remind this Committee that the ESRD Program has been an extraordinarily successful one in keeping literally tens of thousands of people alive and in allowing them to continue to lead productive lives. Kidney patients work as physicians, lawyers, accountants, nurses, homemakers, students, secretaries, bankers, and in many other occupations. As noted in Richard Rettig's study, "Implementing the End-Stage Renal Disease Program of Medicare," this program has had a high degree of cost containment. The cost per patient, in real dollars, has actually decreased since 1973. This has not generally been true of other medical programs.

COMMENTS ON PROPOSED RULE

NAPHT has always had as its foremost concern that all people needing treatment for irreversible kidney failure have access to that care, a major objective of P.L. 92-603, and that the care available be of the highest possible medical quality. The Proposed Rule as published in the February 12, 1982, Federal Register is particularly troublesome because of its potential impact on those two issues. The specific comments that we offer reflect our concerns about access to care and quality of care.

NAPHT recognizes that there is need for some changes within the End-Stage Renal Disease Program. However, the Proposed Rule puts too many patients at too great a risk. According to the analysis by the Health Care Financing Administration (HCFA), "These rates would result in reimbursing 46 percent of all hospital-based facilities and 28 percent of all independent facilities at a rate per treatment below their current costs for in-facility dialysis." This analysis does not indicate how many of these facilities have a sufficient percentage of their patients on home dialysis to offset the losses incurred by the in-center patients. Nor does this analysis indicate where other facilities are or are not available to care for patients in units where costs are above the proposed new reimbursement rates. If these units are not able to offset these losses, they are at financial risk and may be forced to close. The fate of the patients they treat - both in-center and at-home - is of great concern to us.

Because we believe that this Proposed Rule has the potential to do so much damage to both access and quality, we are asking that the rule be withdrawn, more data collected and analyzed, and that the methodology be revised to assure both access and quality. HCFA must demonstrate, not just assume, that access to care is protected before implementing a new payment methodology of this magnitude. So far, they have not done so.

Our written comments on the Proposed Rule contained a number of suggestions for changes we feel should be incorporated into the methodology. I would like to submit those comments for the record (Attachment A), and briefly summarize them. I will also make several suggestions for potential legislative action.

1. The data base is very old. The costs used in this analysis were from 1977-1979. We therefore recommend a specific adjustment for inflation be used in these calculations.

2. The methodology is biased against hospital-based units which have the higher percentage of patients at home. Each treatment location has its merits, but all are interdependent. We therefore

recommend that the basic component costs for hospital-based facilities be developed from hospital data, while continuing to develop basic component costs for independent units from the data for all facilities.

3. There is potential for abuse of the composite nature of the new rate. The current target rate reimbursement program has a number of specific service requirements. We recommend that all these be retained under the new composite rate.

4. There has been a great deal of concern among patients that this proposal intends to close units and send unwilling and/or unsuitable patients home. Home treatment is NOT suitable for many patients for either medical or environmental reasons. Home hemodialysis requires a suitable partner. Any form of home therapy requires space for supplies. Not every patient has these available. Lower socioeconomic status can be correlated with less home dialysis. Units serving predominately poorer populations, therefore, may not be able to benefit from the composite nature of the rate. The Proposed Rule assumes that all units can send patients home. Units which cannot send a significant number of patients home must be protected so that the patients they serve are protected. We therefore recommend that the "atypical patient mix" basis for requesting an exception rate SPECIFICALLY include those units which cannot legitimately send a significant number of patients home for either medical, environmental, or economic reasons.

5. NAPHT recommends that the 100% cost reimbursement for home dialysis equipment be retained.

6. Dialysis is usually a thrice-weekly procedure. Patients cannot live without this therapy. Therefore any disruptions in the delivery system are life-threatening. Yet the Proposed Rule recommends implementation on the date of publication of the Final Rule. We consider this an irresponsible proposal. Changes must be implemented carefully and gradually in order to protect patients. NAPHT recommends that the effective date of any new reimbursement rate be AT LEAST 30 days after publication of the new rate and that any facility with current rates in excess of the new rates be given a phase-in schedule over a MINIMUM of 12 months to allow them to adjust to the new lower rates.

OTHER COST CONTAINMENT RECOMMENDATIONS

NAPHT recognizes the legitimacy of the government and public's concerns about the high cost of the program. We are NOT seeking to protect the current system when we recommend that the Proposed Rule be withdrawn; we are seeking to protect patients. In the interim, some money-saving measures could begin. Specifically:

1. Non-productive expenditures should be eliminated. There is simply no excuse for inappropriate billing such as double billing for physician services, billing for "no-shows," etc. HCFA should institute better review processes to eliminate these expenditures. Consideration should be given to the use of single or regional intermediaries for better management control. Fraud should be prosecuted.

2. Current high cost facilities should be reviewed. Existing exceptions should be immediately reviewed, beginning with the facilities with the those with the highest costs and progressing downward. In this way, adjustment begins with those facilities which are potentially the least efficient. Money can be saved without jeopardizing a large number of patients.

LEGISLATIVE RECOMMENDATIONS

I will now address several issues which we believe should be the subject of legislative as well as administrative actions.

A. Patient Choice and Patient Incentives

As part of our analysis of the Proposed Rule, NAPHT surveyed about 100 of our chapter presidents and directors. One message became very clear. PATIENTS WANT CHOICE AND INCENTIVES. They want to freely choose their physicians, treatment modalities, treatment locations, and treatment facilities. The Proposed Rule does not offer patients either more choices or incentives; indeed it threatens to constrict those choices even further by reducing the number of available facilities. We urge this Committee to carefully consider ways to provide incentives and choices to patients as well as to facilities and providers. Several posssibilities include:

1. sharing the savings of home dialysis between centers and patients.
2. providing paid aides for home dialysis for those who do not have suitable family members as partners.
3. waiving the 20% coinsurance responsibility for home patients who do not have other third-party insurance.
4. authorizing reimbursement for electrical costs incurred in home dialysis.
5. reviewing and conceivably abolishing the certificate of need requirements, which by their nature restrict patient choice, given the cost containment effectiveness of the present and proposed reimbursement rates.

B. Quality of Care

Recognizing the need to contain costs in the ESRD program, NAPHT also recognizes the very real possiblity that lower reimbursement rates may result in fewer or inadequate services. A high rate of reimbursement does not guarantee a high level and quality of care. However, it is impossible to provide good care in the absence of sufficient funding. Some components of good care include adequate staff/patient ratio, adequately trained staff, presence of support services such as social workers, dietitians, psychotherapists, vocational counselors, etc.

Currently we cannot answer the questions (after 10 years of federally funded dialysis therapy):

1. Which comprehensive dialysis programs do a better job of dialyzing and rehabilitating patients of different age groups and diagnoses?
2. Of those facilities which have commendable results, how much does it cost?
3. Conversely, what is the state of health and rehabilitation of patients treated in the lowest cost programs?

To contain costs and insure high quality care, this information is required. There are a number of ways in which this information can be accumulated and used. Examples include:

1. Hold a consensus conference to develop a mechanism to assure quality of care. This would establish what medical, rehabilitation, and cost data are needed to monitor responsibly the quality and cost of this program.
2. Develop a dialysis facility review service, similar to the Joint Commission on the Accreditation of

Hospitals. Medical reimbursement could be conditional upon meeting medical and rehabilitation standards. Quality of care and outcome standards could be developed by a joint task force of physicians and patients selected from the NAPHT, the National Kidney Foundation, and the Renal Physicians Association. Preliminary discussions have been held with members of all three organizations, and there is interest in pursuing these discussions.

3. Develop a similar accreditation and review process implemented by the ESRD Networks.

These suggestions should not be confused with "regulating medical care of doctors." Rather they act in the interests of doctors and patients by insuring quality of care and outcome and serve as a renewable licensing mechanism comparable to the JCAH.

Monitoring the quality of care available should be an ongoing process; it is doubly important now in a period of transition. Public Law 95-292, section 1881(c), mandated that Networks be responsible for "developing criteria and standards for quality patient care" among other things. We recognize that Networks have had limited success in guaranteeing quality. However, they have provided a forum for dealing with quality care issues, and they have played an important role in data collection and in dealing with some patient problems. We therefore recommend that they not be terminated until and unless another and better system for assuring quality, collecting needed data, and dealing with patient grievances is developed.

SUMMARY

In summary, NAPHT believes that the Proposed Rule, if implemented as currently written, creates an unacceptable risk of substantial disruptions in the renal care system with potentially life-threatening results. We again urge this Administration and Congress to carefully re-examine and revise the proposals so that all patients needing care receive that care. As an Association, we are willing and eager to work with other groups, professional, provider, administrative, and legislative, to assure that access to high quality care is guaranteed to all.

We would be happy to answer any questions.

ATTACHMENT A

NAPHT
NATIONAL ASSOCIATION OF PATIENTS ON
HEMODIALYSIS AND TRANSPLANTATION, INC.

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April 9, 1982

Dr. Carolyne K. Davis
Administrator
Department of Health and Human Services
Health Care Financing Administration
P.O. Box 17073
Baltimore, MD 21235

Dear Dr. Davis:

Ref: BPP-126-P

The National Association of Patients on Hemodialysis and Transplantation, Inc. offers the following comments on the Proposed Rule for changes in reimbursement rates for the End-Stage Renal Disease Program. The Association represents approximately 10,000 renal disease patients from all states and U.S. territories. Our comments are based on input from our members, our 33 local chapters, and our Board of Directors.

NAPHT has always had as its foremost concern that all people needing treatment for irreversible kidney failure have access to that care, a major objective of P.L. 92-603, and that the care available be of the highest possible medical quality. This Proposed Rule is particularly troublesome because of its potential impact on those two issues. The specific comments that we offer reflect our concerns about access to care and quality of care.

NAPHT recognizes that there is need for some changes within the End-Stage Renal Disease Program. However, this Proposed Rule puts too many patients at too great a risk. According to your own analysis, "These rates would result in reimbursing 46 percent of all hospital-based facilities and 28 percent of all independent facilities at a rate per treatment below their current costs for in-facility dialysis." Your analysis does not indicate how many of these facilities have a sufficient percentage of their patients on home dialysis to offset the losses incurred by the in-center patients. Nor does your analysis indicate where other facilities are or are not available to care for patients in units where costs are above the proposed new reimbursement rates. If these units are not able to offset these losses, they are at financial risk and may be forced to close. The fate of the patients they treat - both in-center and at-home - is of great concern to us.

Because we believe that this Proposed Rule has the potential to do so much damage to both access and quality, we are asking that the rule be withdrawn, more data collected and analyzed, and that the methodology be revised to assure both access and quality. Specifically, we offer the following comments:

A. GENERAL NATURE - This Proposed Rule makes significant changes in reimbursement methodology in order to encourage home dialysis and save tax dollars. While incentives are theoretically provided to both facilities and physicians to encourage home dialysis, we see no incentives for patients. The assumption that lowering of costs will lower co-insurance requirements for patients and therefore serve as an incentive to them is overly simplified. Because home dialysis charges will increase under the Proposed Rule, co-insurance costs to home patients will also increase.

We recommend that any proposal consider specific incentives for patients. Patients want more choices. They want to choose their physicians, treatment modalities, treatment location, and treatment facility. This Proposed Rule does not offer patients either more choices or incentives; indeed it threatens to constrict those choices even further by reducing the number of available facilities.

There are a number of incentives which could be offered to patients to encourage utilization of home dialysis. Many of these incentives would require legislative authorization. We urge HCFA to consider specific patient incentives for home dialysis and include such incentives, where possible, in the current regulations and recommend legislative changes, where necessary, to provide other patient incentives. Examples of possible incentives for patients include: sharing of the cost savings between patient and facility, waiving the co-insurance responsibility for home patients without third-party insurance, and authorizing reimbursement for increased water and electrical costs. Given the cost containment effectiveness of the present and proposed reimbursement rates, certificate of need requirements, which by their nature restrict patient choice, should be re-evaluated and conceivably abolished.

NAPHT recognizes that a high rate of reimbursement does not guarantee a high level and quality of care. However, it is impossible to provide good care in the absence of sufficient funding. Some components of good care include adequate staff/patient ratio, adequately trained staff, presence of support services such as social workers, dietitians, psychotherapists, vocational counselors, etc. We fear that a lowered reimbursement rate threatens these components of good care.

Monitoring the quality of care available should be an ongoing process; it is doubly important in a period of transition. ESRD Networks were established by regulation as part of the implementation of P.L. 92-603 and further defined in P.L. 95-292. Section 1881(c) mandated that Networks be responsible for "developing criteria and standards for quality patient care" among other things. In your testimony before the Senate Finance Health Subcommittee on September 15, 1981, you stated that the Administration intends to eliminate the Networks as part of the 1983 Budget. We recognize that Networks have had limited success in guaranteeing quality. However, they have provided a forum for dealing with quality care issues, and they have played an important role in data collection and in dealing with some patient problems.

Although this Proposed Rule does not specifically address the continued funding of Networks, we believe that the functions they perform must be continued. We therefore recommend that they not be terminated unless another and better system for assuring quality, collecting needed data, and dealing with patient grievances is developed.

Any quality monitoring process must have significant patient input. Kidney patients develop a great deal of knowledge about their disease. The very nature of home dialysis requires such expertise. Patients cannot, of course, replace health professionals in any quality assurance plan, but they can and must be partners with them.

NAPHT stands ready to work with your staff in developing a good quality assurance mechanism. In Congressional testimony on several occasions, we have offered specific suggestions on some ways of achieving quality assurance; we hope to help your office implement some of these suggestions, which include the following:

1. Hold a consensus conference to develop a mechanism to assure quality of care. Agreement on basic outcome morbidity as well as mortality measurements of quality would be a first step in monitoring that quality.

2. Develop a dialysis facility review service, similar to the Joint Commission on the Accreditation of Hospitals. Financial reimbursement could then be conditional on meeting specific quality standards. This review service should include patients as well as physicians and other health care professionals.

B. PAYMENT FOR DIALYSIS TREATMENTS - As already noted, we have very serious reservations about these proposed rates of reimbursement. The basic concern is, of course, the number of facilities which currently have costs above the proposed new rates. Further we have a number of specific objections to the data base and methodology employed in arriving at the new rates:

1. The data base is very old. The costs used in this analysis were from 1977-1979. No adjustment was made specifically for inflation. Although there have been technological changes (such as shorter dialysis times, dialyser reuse, etc.) which have allowed inflation to be offset to some extent in the past, it is not appropriate to assume that this will occur in the future. We therefore recommend a specific adjustment for inflation be used in these calculations.

2. The methodology is biased against hospital-based units which have the higher percentage of patients at home. Each treatment location has its merits, but all are interdependent. A home program cannot survive without the back-up of a dialysis center. Independent facilities cannot survive without the support of hospital-based units. Use of all facilities to develop the base median labor and nonlabor components favors the independent units. The application of separate percentages of home patients to these median costs yields a strange result: the basic labor component for hospital-based units is LOWER than the basic labor component for independent units; yet the average audited labor costs were $20 HIGHER for hosital-based units than for independent units. We therefore recommend that the basic component costs for hospital-based facilities be developed from hospital data, while continuing to develop basic component costs for independent units from the data for all facilities.

3. We question the adequacy of the bad debt provisions outlined in the Proposed Rule. We believe that some of the costs, including return on equity, which are not "Medicare allowable" costs, are nonetheless "real" costs. Facilities must obviously cover real costs to stay in business.

4. There is potential for abuse of the composite nature of the new rate. The current target rate reimbursement program has a number of specific service requirements including the provision of dialysis supplies, equipment maintenance, administrative and health care support for home patients, and the provision of a "paid aide where necessary" for home dialysis patients. There is fear in the patient community that home patients will provide a source of income for facilities (to either offset losses on in-center patients or to increase facility profits) without receiving appropriate services. We therefore recommend that all the SERVICE requirements of the current target rate program be retained under the new composite rate.

5. Medical care decisions should be made by physicians. The method of treatment should be selected by patient and physician based on the medical needs of the patient and the life circumstances of that patient. It is inappropriate for the Health Care Financing Administration to state that "CAPD is the preferred treatment for many patients," and to favor one form of treatment over another. We recognize that currently there are disincentives for home treatment and welcome the removal of those disincentives. However, basing a new rate on the apparent assumption that continuous ambulatory peritoneal dialysis (CAPD) will become the treatment of choice for a large number of patients is inappropriate, particularly since CAPD is a relatively new therapy which has not been proven both safe and effective over a long period of time.

For example, the National Institutes of Health CAPD Patient Registry data for 1981 show a 43% drop-out rate, an 84% hospitalization rate, and a 14% death rate with 1.9 episodes of peritonitis per patient-year, 2.5 hospital admissions per patient-year, and 25.7 days hospitalized per patient-year.[1] The European experience with CAPD is similar with a 43% drop-out rate at one year and a 68% drop-out rate at two years.[2]

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1. Life Table Analyses, National Institutes of Health CAPD Patient Registry, the Registry Pilot Project, "Patient Population Demographics and Selected Outcome Measures."

2. The Lancet, January 23, 1982, page 235.

C. EXCEPTIONS - NAPHT recognizes the need for tighter control of the exceptions process. We were profoundly disturbed to learn that in the past exceptions have been granted without audit of costs. The Proposed Rule notes that it is expected "that under the proposal few facilities would be able to qualify for exceptions to their payment rates." We commend the Health Care Financing Administration for including "isolated essential facilities" as one group which would qualify for exceptions. We urge that the criteria for this group consider patient needs, including reasonable travel times and the full range of treatment modality options. It is impossible for patients to lead meaningful lives and continue to seek employment if they must spend excessive time travelling to and from treatments. The time demands of treatment are substantial; adding excessive travel time makes dialysis treatments a totally consuming activity rather than a means to continue a meaningful life.

There has been a great deal of concern among patients that this proposal intends to close units and send unwilling and/or unsuitable patients home. We know that you recognize that home treatment is NOT suitable for many patients for either medical or environmental reasons. Home hemodialysis requires a suitable partner. Any form of home therapy requires space for supplies. Not every patient has these available. Lower socioeconomic status can be correlated with less home dialysis. Units serving predominately poorer populations, therefore, may not be able to benefit from the composite nature of the rate. The Proposed Rule assumes that all units can send patients home. Units which cannot send a signficant number of patients home must be protected so that the patients they serve are protected. We therefore recommend that the "atypical patient mix" basis for requesting an exception rate SPECIFICALLY include those units which cannot legitimately send a significant number of patients home for either medical, environmental, or economic reasons.

D. ONE HUNDRED PERCENT COST REIMBURSEMENT FOR HOME DIALYSIS EQUIPMENT, INSTALLATION, MAINTENANCE, AND REPAIR - This provision was intended to increase home dialysis and was not eliminated by the Budget Reconciliation Act of 1981. We question the authority of the Health Care Financing Administration to eliminate it and further believe that it is counterproductive to the goal of increasing home dialysis. Although purchase of equipment may be more expensive initially, we believe that it will save money over time. NAPHT recommends that the 100% cost reimbursement for home dialysis equipment be retained.

E. EFFECTIVE DATE - Dialysis is usually a thrice-weekly procedure. Patients cannot live without this therapy. Therefore any disruptions in the delivery system are life-threatening. Yet the Proposed Rule recommends implementation on the date of publication of the Final Rule. We consider this an irresponsible proposal. Even if every assumption in the Proposed Rule is true and increased home dialysis, better management, and the exceptions process protect the 46% of hospital-based facilities and 28% of indpendent facilities with current costs above the new rates, this cannot happen instantly. Revising management systems takes time, filing an exception request takes time, developing a home training program takes time, and training patients to go home takes time. Changes must therefore be implemented over time. NAPHT therefore recommends that the effective date of any new reimbursement be some time after publication of the new rate and that any facility with current rates in excess of the new rates be given a phase-in schedule to allow them to adjust to the new lower rates. There should be AT LEAST 30 days after the announcement of the new rates before implementation. For facilities which have current rates substantially above the new rates, we recommend implementation occur in several steps over AT LEAST a 12 month period. For example, if the current rate is $50 above the new rate, an intermediate rate $25 above the new rate should be allowed for the first year after the effective date of the regulations and the final rate should not be effective for AT LEAST one year.

Although this proposed rule is limited to the new reimbursement rate, the NAPHT would like to make several additional observations and recommendations. Our concern remains that all patients have access to needed therapy. We also recognize the legitimacy of the government and public's concerns about the high cost of the program. We are NOT seeking to protect the current system when we recommend that the Proposed Rule be withdrawn; we are seeking to protect patients. We do recommend some interim money-saving measures, however.

1. Non-productive expenditures should be eliminated. There is simply no excuse for inappropriate billing such as double billing for physician services, billing for "no-shows," etc. Whether such billing occurs as a result of poor management or because of fraud is irrevelant. HCFA should institute better review processes to eliminate these expenditures. Consideration should be given to the use of single or regional intermediaries for better management control. Fraud should be prosecuted.

2. Current high cost facilities should be reviewed. It is unfortunate that exceptions have been so easily

granted. Existing exceptions should be immediately reviewed, beginning with the facilities with the highest costs and progressing downward. In this way, adjustment begins with those facilities which are potentially the least efficient. Money can be saved without jeopardizing a large number of patients.

The National Association of Patients on Hemodialysis and Transplantation, Inc. is committed to an efficient and effective renal program. We offer our ongoing assistance in the development of a payment methodology which assures that all patients receive high quality care in an efficient and effective manner. We would be happy to provide any additional information needed and urge again that this Proposed Rule be withdrawn and revised so that all patients are protected.

Sincerely,

John Newmann

John Newmann, Ph.D., M.P.H.
President

STATEMENT OF RICHARD M. FREEMAN, M.D., PRESIDENT, NATIONAL KIDNEY FOUNDATION, INC., AND DEPARTMENT OF MEDICINE, UNIVERSITY HOSPITAL, IOWA CITY, IOWA

Dr. RICHARD M. FREEMAN. Congressman Rangel, Congressman Pickle, my name is Richard M. Freeman. I am president of the National Kidney Foundation. I represent not only doctors but social workers, dieticians, nurses, lay volunteers, and especially patients.

When I attended some oversight hearings in the Senate about 4 weeks ago, we were concerned about these regulations and concerned from two major standpoints. We were particularly concerned about the impact of the regulations on the pediatric community.

This is a group of patients who require more than the usual amount of care, and there was great concern that pediatric dialysis units might be under jeopardy. We are still concerned about that, and the subsequent comments later in the day will emphasize that even more.

We were also concerned about the rural community, since it appears on the basis of analysis of at least one rural community, Network, No. 8, Inc., which includes Iowa and Nebraska, that although this area accounts for 1.3 percent of the dialysis population, in fact, it would be accounting for 2.3 percent of the dialysis savings.

There is concern about these communities because large volumes of patients are not as easily obtained. Acquiring nurses of high standard in rural communities may be difficult, too. You may not realize that some people would prefer to go to New York City than to come to Iowa, but nurses are in this category as well.

We have broader concerns since these past 4 weeks because we have had input from many areas. We think the hospital based facilities are in some jeopardy. I think also the independent facilities are in some jeopardy. The written testimony will essentially speak to these issues in more detail.

I would like to make one point, however, related to the intent of these regulations as an incentive for home hemodialysis. We are concerned that that may not be so. Although, according to the regulations, the reimbursement for in-center dialysis would decrease, the reimbursement for home dialysis would actually increase.

Since patients are responsible for 20 percent of these costs, their responsibility actually increases, rather than decreases, with the regulations. We suspect that a home dialysis patient now receiving dialysis in the home, will be responsible for about $750 more tomorrow than he would have last year. We think, therefore, that this is not an incentive in the right direction.

Furthermore, we believe there are now figures available from some of the data obtained by HCFA through Networks that as many as 40 to 50 percent of new patients entering dialysis each year are being trained for the home. I am talking about new patients, not total population. But if you take the new patients as a denominator and put those trained for home as the numerator, it appears that 40 to 50 percent are now being trained for home.

We recognize that peritoneal dialysis is responsible for a lot of this increase. Nonetheless, we have some evidence that home dialysis, which was as low as 11 percent, is now maybe as high as 17 percent. So improvements are being made.

We are also concerned that such regulations may indirectly lead to selection of patients for dialysis, and while we realize that this was not the intent of Congress, it greatly concerns us.

About 6 weeks ago, I saw a patient in the renal clinic. I read my note on this patient written in 1972, and it said, "This is a 55-year old woman who is not an ideal candidate for dialysis and transplant because of her age and heart disease." It was clear from my note that I thought this woman would never be dialyzed or transplanted.

Two months later, I saw my note that said, "Perhaps we can maintain this patient with peritoneal dialysis until Federal funds become available in 1973." Indeed, the Federal funds did become available and the woman has been alive for 10 years. She has never been hospitalized and has clearly benefited from Federal support.

I make this comment for two reasons. One, to thank you for the support she has had, she is alive now because of Federal support; and to point out that our ability as physicians to select patients who will benefit is not so great, and we fear being put in that position again. I want to point out that I realize this was never the intent of Congress related to these regulations.

Finally, I want to point out that volunteer efforts are underway in many places to try to cut costs, but we must teach each other how to cut costs. Physicians are trained to save lives, not to cut costs. We have got to learn more about how to cut costs. In the State of Iowa, we have been able to buy dialyzers together as a group in order to cut costs. We have changed our billing practices in order to cut costs. We have done a variety of things. We have taken what I call a Cadillac home-dialysis program and made it a Chevrolet program, nonetheless, the patients recognize why we are doing this. They do not complain if it is done properly and if their health is taken into consideration.

In summary, I think the regulation should be reworked so that patients are not in any potential jeopardy and the National Kidney Foundation is very anxious to help in any way we can to that end.

Thank you.

[The prepared statement follows:]

STATEMENT OF RICHARD M. FREEMAN, M.D., PRESIDENT, NATIONAL KIDNEY FOUNDATION, INC.

The National Kidney Foundation believes that the regulations should be withdrawn and rewritten for the following reasons:

1. The reimbursement rates appear to be based more on the need to save a specific amount of money than on any analysis of accurate cost data.
2. Dialysis units in rural areas may be under special jeopardy as are units treating primarily pediatric age patients.
3. Continuous ambulatory peritoneal dialysis (CAPD) is overemphasized as cost effective therapy superior to home hemodialysis in the absence of confirming data.
4. Inflation is largely ignored as a factor influencing reimbursement.
5. The regulations may indirectly decrease kidney transplantation.

An Evaluation of the Proposed Prospective Reimbursement Rates for Dialysis Services

(Federal Register, Vol. 47, No. 30, 6556-6582, February 12, 1982)

Proposed by the National Kidney Foundation, Inc
2 Park Avenue
New York, New York 10016

Richard M. Freeman, M.D.
President

Comments Concerning Federal Register 47:6556-6582, Feb. 12, 1982
42 CFR Part 405. Medicare Programs: End Stage Renal Disease Program; Prospective Reimbursement for Dialysis Services

I. Introduction - p.6556-6558	No comment.
II. Proposed Regulatory Provisions, p. 6558-65-61 C. Exceptions	We are concerned that the rural unit with relatively low utilization, that serves a population remote from a major population center, be able to achieve an exception readily and in a timely fashion. Failure of such a facility would limit access to care for the population served. We are also concerned that few if any facilities will be able to relate their excess costs due to an atypical patient mix to costs of other facilities with a similar patient mix, in view of HCFA's previously demonstrated inability to generate accurate cost data in the ESRD Program.
G. Revision of Rate Setting Methodologies and Payment Rates	It is mandatory that the rates be adjusted annually according to a previously determined and generally accepted index of change in the cost of living. It is unacceptable to leave open the frequency and method by which such changes will be made.
I. One Hundred Percent Cost Reimbursement for Home Dialysis Equipment, Installation, Maintenance, and Repairs	PL95-292 provided a mechanism whereby the Secretary (of HHS) could reimburse the full cost of home dialysis equipment, installation, maintenance, and repair. The proposed regulations propose to discontinue this practice by regulation, thus abolishing the statutory provision. We agree that this would simplify administration of the program and the concept of a composite rate, but we are deeply concerned with the concept of bureaucratic abrogation of a statute. Furthermore, we believe the action will be a disincentive toward increasing patients receiving home dialysis.
III. Rate Setting for Dialysis Treatment A. General Overview	We concur with the concept of composite rates, with the concept of different rates for hospital-based and independent facilities, and with an area wage rate adjustment as prescribed by Section 2145 of PL97-35. We are aware that the political and economic reality is that there will be a reduction from present reimbursement levels as a cost saving measure as emphasized in the introduction (p. 6556), where "high and steadily rising cost of the program and the burden it can place on the Medicare trust funds..." is identified as the major problem with a program that "has been generally successful in protecting renal disease patients against catastrophic costs of medical care." It should, however, be emphasized that the rising costs are almost entirely related to increasing numbers of beneficiaries, and that there has been an actual decrease in the cost per beneficiary treated in constant dollars each year since the start of the program.

The commitment of HCFA to cost reduction is nowhere more eloquently stated than in a memo in the early fall of 1981 from Carolyne K. Davis, Administrator of HCFA, to Richard Schweiker, Secretary of HHS, in which she states: "Where to set the reimbursement rates for outpatinet maintenance dialysis depends upon the savings that must be achieved and the type of facility from whose present reimbursement the savings will be taken" (p.4, underlining by the author of this evaluation). Indeed, this statement clearly indicates that the end result is paramount, and the means by which it is achieved is secondary. The proposed regulations, and their totally, and erroneously, contrived methodology, amply support this concept.

b. Using Cost Per Treatment as the Basis for Our Rate

We concur that reimbursement should be based on the cost of efficiently and economically operating a facility. We agree that a payment per treatment session is the most obvious unit of reimbursement and approve this concept. We deplore the fact that HCFA does not have accurate or current cost data, and proposes, therefore, to establish a reimbursement level "at what appears to be an adequate level to reimburse an efficiently and economically operated facility."

C. Costs to be Included in Setting the Rate

We concur that the cost of furnishing routine ESRD laboratory services should be included in the cost per treatment calculations.

D. Costs of In-Facility Treatment

We believe the audits conducted in 1980, of 1978 and 1979 cost data, and from which costs were adjusted, should be made readily available to ESRD providers and interested organizations. We also believe the criteria by which "adjustments" were made to audited costs should be made readily available. Finally, the major identified adjustment to independent facility costs is identified as in the area of compensation to administrators and medical directors of ESRD facilities. A limit of $32,000 was "applied." We question whether this limit is reasonable, since the cost of salaries and fringe benefits for many individuals in the health care field with lesser responsibility and who supervise fewer individuals, some funded by federal funds, now clearly exceeds this compensation.

D. Costs of Home Dialysis

It is unacceptable that HCFA does not have accurate cost data on home dialysis, since all billings and payments are approved by HCFA. A survey covering only 5% of ESRD facilities with home programs is not representative, even though it covers 30% of home patients, because it includes ten of the thirteen largest programs, and is therefore biased by the largest programs, which should operate more efficiently and cost effectively by economies of scale alone. Thus, the real costs of a truly representative sample of home dialysis facilities would be underestimated by the survey, and do not accurately reflect the average cost per treatment of home dialysis as represented in the proposed regulations. Moreover, because all net growth in home dialysis is now in the rapidly growing areas of CAPD, and since CAPD may be as costly as home hemodialysis, and since CAPD supply costs are increasing at an extremely rapid rate, any survey of home dialysis facilities is of no value without knowledge of the proportion of patients on home hemodialysis vs. CAPD.

E. Rates for Independent and Hospital-Based Facilities

It is deplorable that HCFA has to "ascertain an efficient level of costs." The actual costs of both hospital-based and independent facilities for a recent reference year should be known by HCFA and then should be appropriately adjusted for inflation following the reference year.

F. Composite Rates for Home and In-Facility Dialysis

We have profound concern regarding, not the concept of a composite rate, but the factors applied in arriving at the actual reimbursement rate determined from the composite rate concept, and the potential effect of an overwhelming emphasis on home dialysis or transplantation.

First, as indicated above, we believe the cost of home dialysis has been significantly underestimated by the survey conducted. Second, "the composite rate would pay marginally less than the full cost for in-facility dialysis (1978-1979 costs) because of the home component in the facility." This would mandate that, to survive financially with the composite rate, facilities would be forced to send more patients home. We are concerned that the savings to the facility of sending patients home, having been overestimated by HCFA, will not offset the loss suffered by the facility in its in-facility operation, particularly since out-dated cost information without any adjustment for inflation was used to estimate in-facility costs.

We are also concerned that the incentive to place patients on home dialysis will lead to actual decreases in renal transplantation since, to a large extent, the same patients are home dialysis or transplant candidates. The facilities may be forced to keep potential transplant candidates on home dialysis to survive financially.

G. Adjusting Rates for Geographic Wage Differences

Although we agree with this concept, we believe that prospective, not current or even obsolete wage indices, must be used to calculate prospective reimbursement rates.

I. Summary of Proposed Methodology and Rates

The use of the median of Medicare-audited and Medicare-approved facility costs, based on 1977, 1978, and 1979 cost data (never made public) with no allowance for the 12% or greater annual inflation in the intervening 3-4 years, would result in reimbursement rates less than those costs to 46% of hospital-based and 28% of independent facilities, applying the erroneously calculated reimbursement rates of $132 per treatment for hospital-based and $128 per treatment for independent facilities. Application of the average area wage rate factor of 1.0418 to the published costs, correctly calculated, would result in an average reimbursement of only $124.58 (p.6565, $49.61 x 1.0418 + $72.90 = $124.58) for independent facilities and only $128.33 (p. 6565, $46.31 x 1.0418 + $80.09 = $128.33) for hospital-based facilities.

These corrected calculated costs would result in reimbursement of less than 1977-1978-1979 actual costs to approximately 50% of hospital-based and 31% of independent facilities. We seriously doubt that such a large percent of facilities can achieve sufficient cost reductions, even by increasing home dialysis substantially, to survive without sharply limiting quality of care, and without beginning to limit access to care. A survey of ESRD Network 8 indicates an average decrease in current reimbursement levels of 25%, with a range of decrease from 10% to 38%, and an average per-treatment decrease in reimbursement of $40. The decrease is disproportionately great for rural facilities. We are deeply concerned that some facilities will cease operation nationwide, and that a disproportionate number of rural facilities will close. This is not acceptable in a humanitarian sense or as a matter of public policy.

V. Additional Issues

A. Prospective Rates for Self-Care Dialysis Training

It is inconceivable and unacceptable that HCFA has no reliable cost data concerning self-care dialysis training, since HCFA purports to advocate home dialysis so strongly as a means of reducing costs. Facilities are now paid their approved reimbursement rate plus $20 for each training session, an amount most home training facilities find does not cover the cost of home training. The proposed regulations would maintain the $20 differential, but since the screen would be reduced substantially, Medicare would pay less per training session than now. We suggest that HCFA move promptly to address their negligence in this regard, and obtain accurate cost date for home dialysis training.

B. Prospective Reimbursement Rates for Peritoneal Dialysis and New Dialysis Techniques

We again cannot understand HCFA's lack of accurate cost data concerning peritoneal dialysis. We urge, particularly in view of the rapid growth of CAPD, which now accounts for all net growth in home dialysis in this country, and in view of the very rapidly rising costs for necessary CAPD supplies, that HCFA undertake a prompt determination of costs of peritoneal dialysis, particularly CAPD, and of pertitoneal dialysis and CAPD training.

We believe it is inappropriate for HCFA to judge CAPD a "preferred treatment for many patients." Preferred to what - to home hemodialysis - to transplantation? We are also unsure of the cost saving advantages of this form of treatment to Medicare since supplies now cost $12 per exchange, or $17,500 per patient per year, exclusive of training costs, catheter placement costs, costs of treatment of peritonitis, hospitalization costs, tubing change costs, costs of laboratory work, physician costs, etc. There is urgent need for accurate cost data for CAPD, available only to HCFA.

D. Patient Billing	Since PL97-35 still permits home dialysis patients to bill Medicare for supplies and equipment, Medicare will pay twice for home dialysis supplies in the absence of some means to reconcile facility and patient payments for home dialysis. We have no confidence that HCFA can maintain sufficient records to prevent such double payment, since HCFA's track record with regard to all other cost data is so poor.
F. Home Dialysis Aides	We seriously doubt that many facilities could afford paid home dialysis aides under the proposed reimbursement rates.
Appendix I - Regulatory Impact and Flexibility Analyis (p. 6577) Overall Effects (Col. 3)	We believe it is naive and inaccurate to state that "Since we do not expect any reduction in quality of care, the improved cost effectiveness of the dialysis delivery system would justify these changes." Of course, a reduction of 25% in average reimbursement (ESRD Network 8 Survey) will result in a reduction of quality of care, and may limit access to care, both geographically and with respect to high care patients, especially the elderly with significant other disease.

Chairman RANGEL. Thank you, Doctor.

Mr. Calvin Bland, executive director, St. Christopher's Hospital for Children in Philadelphia.

STATEMENT OF CALVIN BLAND, EXECUTIVE DIRECTOR, ST. CHRISTOPHER'S HOSPITAL FOR CHILDREN IN PHILADELPHIA

Mr. BLAND. Good morning, Congressman Rangel and Congressman Pickle.

My name is Calvin Bland, and I am the executive director of St. Christopher's Hospital for Children, a pediatric, nonsectarian medical center located in north central Philadelphia, and the major pediatric affiliate of Temple University School of Medicine.

I would like to review with the subcommittee the impact of the proposed renal dialysis regulations in the face of actions at the Federal and State level that have profound implications for inner-city hospitals serving indigent patients. I will use the experience of my hospital to illustrate the common problems confronting similar institutions.

St. Christopher's is one of the largest providers of indigent care in Pennsylvania, serving both as a tertiary referral center and as the major source of primary care for tens of thousands of children. Each year over 150,000 children are treated. A high percentage of medicaid and uncompensated care has placed a severe financial burden on the hospital.

Losses from operations in the past fiscal year exceeded $2.8 million, despite a no-holds barred effort to control costs. Today we find ourselves moving closer and closer to the point where we will be forced to limit care to those unable to pay or close our doors.

To date, the cuts that have occurred in medicaid and in the health block grants have fallen hardest on St. Christopher's and urban hospitals serving a disproportionate share of the poor—especially children's hospitals. The cumulative impact of these cuts has placed the hospital under serious financial pressure and threatens our future viability. Because of this, we have absolutely no remaining ability to absorb or shift any deficits associated with underfunding of the ESRD program.

It is important that you understand the impact that Federal and State cuts are having because only in this light can the Committee on Ways and Means form a realistic conclusion on the ability of hospitals to continue service delivery under the proposed ESRD regulations. For this reason, I respectfully request the committee's indulgence as I review the more significant program reductions which affect my hospital.

Although the full impact of the block grant legislation will not be felt for another 6 to 12 months, it is already clear that these cuts will seriously affect us. Funding for our children and youth program has faced a $100,000 decrease this year and may be phased out completely next year.

In the coming year, there will be no funding for genetic disease testing and lead paint screening funds will be reduced by 10 percent or more. Family planning, dental services, early intervention for children with mental retardation and improved nutrition for women, infants, and children will all be reduced. As this committee knows well, I could go on and on.

St. Christopher's is dependent on the medicaid program for over 40 percent of its revenues. Inadequate medicaid reimbursement already causes a significant financial shortfall for us. For example, medicaid now pays the hospital only $15 for an emergency room visit and $10 to $15 for many complex radiological and laboratory studies. Moreover, many necessary children's services are considered nonreimbursable. As a result, when these services are required, we provide them free of charge.

Now the State of Pennsylvania, reacting to increased discretion and Federal cuts, is developing regulations to limit hospital per diem increases to 7.8 percent. The State is also developing a series of other cost saving measures for the medicaid program, the details of which have yet to be announced.

St. Christopher's, located on the New Jersey/Pennsylvania border, has also been adversely affected by that State's medicaid cuts. Currently, the New Jersey medicaid program under-reimburses the hospital for services we provide to its recipients.

Now New Jersey has implemented a regulation that denies payment for any elective care sought outside the State unless such care is unavailable in New Jersey. I will share with you one example to illustrate the hardship such a seemingly simple ruling can cause.

St. Christopher's Hospital for Children has the third largest cystic fibrosis center in the country. No comparable center exists in southern New Jersey. Many of St. Christopher's cystic fibrosis patients and their families have been coming to the hospital for 10 and 20 years. They have developed longstanding relationships with physicians and hospital staff which enhance both clinical and emotional support.

We are now faced with the choice of providing free care to cystic fibrosis victims from New Jersey in order to maintain continuity of care for longstanding patients with only a few years of life remaining, or turning these patients away and referring them to providers in southern New Jersey not as experienced at providing the care they need and want.

Let me now turn to my most immediate concern in appearing before you today. Although all of these cuts have been difficult for us to absorb, we have managed so far to avoid major programmatic cuts. Now, for the first time, the proposed regulations threaten to force the closure of a major hospital service: our pediatric end stage renal disease program.

St. Christopher's Hospital for Children is one of only 16 children's hospitals in the country providing renal dialysis services. Each year 10–20 successful transplantations are performed and close to 4,000 dialysis treatments are provided at home or at the hospital.

The cost of caring for these patients is necessarily higher than the average cost of caring for other patients with ESRD. Our cost per treatment is more than twice the proposed composite rate. These higher costs are the product of many factors, including the following:

Higher overhead rates: A national study has documented that the complexity and intensity of specialized services provided in children's hospitals are associated with a substantially higher overhead factor.

Dynamic and aggressive nature of treatment patterns: The goal of pediatric ESRD programs is successful kidney transplantation. A 1981 survey of children's hospitals' ESRD programs indicated that the average time between initiation of dialysis and transplant was less than 7 months and that 47 percent of the patients had already undergone a transplant. Overall, pediatric programs experience patient turnover rates of approximately 50 percent per year. Thus, these programs have higher costs due to continuous, intensive evaluation and orientation of newly diagnosed patients as well as preparation of children and parents for transplantation.

Unique needs of pediatric ESRD patients: The disease characteristics of these patients present greater clinical challenge than those of adults and require higher staff to patient ratios. Because of the range of body size and growth factors, closer monitoring of laboratory values, medication levels and fluid volumes is required. A large and very costly inventory of specialized equipment must be kept on hand.

Regional resource: St. Christopher's Hospital for Children services as a regional resource for ESRD patients and families, conducts research into the causes and treatment of pediatric ESRD and trains health professionals in this specialty.

HCFA has proposed a composite rate, aimed at encouraging home dialysis. Ironically, the effect for our hospital will be a clear financial disincentive to home dialysis. Because nearly 50 percent of our patients dialyze at home and bill medicare directly for supplies and equipment, we will not receive the composite rate for these patients. Yet, we provide training, continuous follow-up, back-up dialysis, and other services to these patients.

Furthermore, the center-based rate has been decreased to reflect the home-based caseload. Thus, we will be severely penalized for our current high rate of home dialysis and the financial penalty will increase with growth of home dialysis. This serious defect must be corrected.

More importantly, the proposed rate will meet less than half of our costs. As a remedy, HCFA has proposed an exceptions process for providers serving an atypical patient population. All that is clear so far is that this process will be stringently and rarely applied.

The burden of proof and uncertainty is placed on the hospital. Our experience with the existing exceptions process has proven it to be extremely lengthy, complex and at times inadequate. We have yet to reach final settlement for 1979, 1980 or 1981—over $500,000 is involved.

We have provided HCFA with specific and detailed recommendations for improvement of the proposed exceptions process. These comments, a copy of which has been provided to the subcommittee, recommend clarification of and changes in data requirements, timing, procedures and transitional measures.

The exceptions process must provide for the granting of appropriate and timely exceptions to the proposed reimbursement. Excessive financial uncertainty in the short term may lead to unnecessary elimination or reduction in pediatric ESRD programs.

However, a more rational alternative to the exceptions process would be development of separate prospective rates for pediatric facilities based on current and comparable cost experience.

To summarize: We expect that the proposed regulations will force us to close our pediatric end stage renal disease program by threatening a large reimbursement shortfall. Any regulation that requires a hospital to absorb a major shortfall or results in the need for cost shifting to other payors is unreasonable and inequitable. In any case, our hospital has already reduced its operations to the bone and with our high indigent caseload and the blows dealt by medicaid, block grant, and other cuts, we clearly do not have the resiliency to absorb, nor the capability to shift, the cost of such a program.

In closing, I would recommend that this subcommittee solicit from HCFA the assurance that before final regulations are published, a more reasonable and dependable methodology will be developed to recognize the costs of ESRD programs in institutions like my own. These institutions provide a vital service to unique patient populations and in the process incur costs that far exceed the proposed dialysis rate.

Thank you for this opportunity to appear before you this morning. I will be very pleased to answer any questions, comments or concerns you might have.

Chairman RANGEL. Thank you, Mr. Bland.

Mr. Pickle.

Mr. PICKLE. Mr. Chairman, I know we have a lot of people to testify and I am particularly interested in hearing what the administration says.

I am impressed that all three panelists urge that the regulations be held up or withdrawn, or a new proposal submitted. I am impressed that the first person, Margaret Diener, noted that patients want choice and incentives, but that the proposed rules will not give patients choice because the rules may mean a reduced number of available facilities.

Be a little more specific with me. How will it reduce available facilities?

Dr. RICHARD M. FREEMAN. The concern is it has a potential to reduce the available facilities, because of the lower reimbursement rates. There would be fewer facilities available. A number of providers have already indicated they have to close some of their facilities.

Mr. PICKLE. You say if they go to home treatment and the rules go into effect, that the hospital could not stay open or that the services could not be provided?

Dr. RICHARD M. FREEMAN. There will be certain places which have hospital units, they feel they will have to close. Hospitals are under great stress to constrain their costs, too, so that if they have a major deficit in the budget, therefore they may be unwilling to stay open and such patients will not have a choice of center for dialysis. That choice will be removed.

Mr. PICKLE. Well, would they also be able to go take their treatment at home?

Dr. **Richard M. Freeman**. Not all patients can be trained, unfortunately, for home. In certain areas, you see, there may be one dialysis unit in a 50-mile radius, so that patient no longer has a choice. If the unit closes in that area, the patient would have no choice.

Mr. **Pickle**. Mr. Bland.

Mr. **Bland**. If I could comment further. St. Christopher's is the only pediatric end-stage renal disease facility in the Delaware Valley. That is a very large metropolitan area, and I can tell you unequivocally and categorically if the proposed regulations are implemented, which we perceive as giving rise to a significant financial deficit for our program, we would have to make a very difficult decision, and that difficult decision might be to close our program.

If we close our program, there are no other children's centers in our area for transplantation or dialysis. You cannot just take a child and move him to an adult center. It is not a mechanical process. It is a very complex physiological service and need which is being met by the pediatric center. So therefore, if we close it is a problem.

Mr. **Pickle**. Is the panel asking for more funds in the overall program or just a delay in the issuance of the rule so that we might have more consideration given to the existing facilities?

Ms. **Diener**. This is John Newmann, the president of our association. He has just arrived and I would like to introduce him.

Mr. **Newmann**. Our written testimony is based upon our concern that all patients have access to care. As we pointed out, the HCFA analysis currently shows that 46 percent of the hospitals' current costs and 28 percent of the independent centers' costs will be above these proposed rates.

We are suggesting that the proposal be withdrawn and redone, and we have made a number of suggestions as to how this could happen. A very important one is bringing the cost data up to date from 1977 to the present due to inflation and asking HCFA to not assume, but to insure that those centers which are at risk will be able to have their patients treated either in their centers or nearby.

And the assumption has been made, but the assurance has not been given. There has been no data analysis of those centers who are at risk. What is their home patient population, will they be able to absorb the deficit cost? And we feel it would be more responsible to know that before implementing the rules.

Mr. **Pickle**. Well, I can understand that.

Under the existing rules with which we have operated in, let us say, the last 5 years, have there been any increases in reimbursements for either hospitals or physicians who treat the patients? Have fees stayed the same while costs kept rising?

Dr. **Richard M. Freeman**. The physician reimbursement is largely a State factor, and it has not increased.

Mr. **Pickle**. In what period of time?

Dr. **Richard M. Freeman**. In almost 10 years. There has been a very slight increase, but essentially none. Hospitals, some have been approved for an exceptions process, and if so they may have had an increase over that period of time. That is the data we are not sure about.

Proprietary facilities have not had an increase for some time. So in general, the cost of the program per patient has gone down rather than up. The problem has been that the program has been successful. We have been saving lives and we have 60,000 people who are alive now. So the problem has been that we have patients alive. No one anticipated 50 years ago that 70-year-old people would thrive on dialysis.

Mr. **Pickle**. And it costs the same.

Dr. **Richard M. Freeman**. And it costs the same. But their lives are as valuable as anyone else's.

Mr. **Pickle**. Thank you, Mr. Chairman.

Mr. **Bland**. One more comment about the adequacy of current reimbursement. As I indicated in my testimony, we have a half million dollars still outstanding for care to end-stage renal disease patients. Now, this is a result of a cost that is in excess of what they call the screen, or $138.

Our costs are about $300. I have described extensively why pediatric hospitals have higher costs. Despite the fact that some of those costs tend to be recognized through the exceptions process, the exceptions process currently is a very cumbersome and lengthy one. When we have a half million dollars that has not been paid to us, we have to go to somebody else to give us that half million dollars to meet our operating needs in the current year. We cannot wait year after year after year for a lengthy appeals process.

So my comment is twofold: The current process is grossly inadequate; and that which is being proposed is grossly inadequate.

Mr. **Pickle**. On the flip side of that argument, the program is costly, but we have saved lives. Yet the administration is proposing rules to try to find a different way to get at the cost because of the tightness of money. They are not trying to not offer solutions. They are just trying to cut costs.

You are just saying that which is proposed is not workable and would hurt your operations.

Mr. **Bland**. That is correct.

Mr. **Pickle**. Thank you, Mr. Chairman.

Chairman **Rangel**. Mr. Bland, I think your case is, in dealing with children, just because they are children they are more helpless, there is turnover, and they are moving on to transplant. You just cannot deal with this problem using the same type of figures. You have to deal with a process that——

Mr. **Bland**. Yes, you have to deal with a process that recognizes the specific and unique characteristics of pediatric ESRD facilities. The goal, to some extent, of adult dialysis is chronic maintenance. The goal of pediatric dialysis is really toward successful transplantation.

Chairman **Rangel**. Why have you not been able to convince the professionals of the uniqueness of what you are trying to do?

Mr. **Bland**. I do not really know.

Chairman **Rangel**. Do you belong to any association?

Mr. **Bland**. Yes, the National Association of Children's Hospitals and Related Institutions has a specific committee on end-stage renal disease. Dr. Gruskin, who is the chairman of our department at St. Christopher's and also chairman of that committee, will speak on a later panel and address that in great detail.

Chairman RANGEL. Do you know whether they have been in touch with the administration as it relates to this?

Mr. BLAND. Yes, they have.

Chairman RANGEL. Who did you say will be speaking?

Mr. BLAND. Dr. Alan Gruskin, on the second panel.

Chairman RANGEL. That is close enough for me not to forget. But will you do me a favor?

Mr. BLAND. Certainly.

Chairman RANGEL. Get a copy of the cases made out for the children that have kidney problems and outline the additional costs involved, and see whether you can send a copy of that to the Secretary, with a copy to me. Because I really do not think that we should be talking about the problem of children involving dialysis and transplants in the same focus with other people. I would like to handle that separately.

So if I do not ask you questions, it is not because I do not like you.

Mr. BLAND. I never thought that for a moment.

Chairman RANGEL. Let me ask some questions. It is good to see you again, Mr. Newmann.

How do you know the providers are providing quality care at reasonable rates? I speak with a lot of people who are not doctors, who are providers, who have a lot of stockholders who are concerned with improving profits, and I would think that that is what their business is and should be.

How do you know? Your association is concerned with access and quality care. How do you monitor those things and costs?

Mr. NEWMANN. We do not know that they are receiving quality care. I think the assumption is that generally around the country they are. However, we receive occasional complaints from patients, and the difficult thing is when we try to follow it up very few patients are willing to be identified and talk directly with their doctor about these complaints for fear of being treated improperly or losing the place, the dialysis unit.

And as you know, the certificate of need process has limited the dialysis units across the country. So when a doctor says go somewhere else there is often nowhere else to go. So many patients have been reluctant to stand up and be counted, although they would offer an unsigned complaint letter.

Our interest, as we suggested in our testimony, is to, as we suggested, have a consensus conference where doctors, patients and the administration would get together to determine the medical rehabilitation and cost data required to properly monitor the program. We have also suggested in the testimony that perhaps a process similar to the joint accreditation of hospitals be developed, on reviewing dialysis facilities for outcome data, cost and quality of care. And that successful review would be dependent upon the renewal of ongoing reimbursement for medicare.

We have spoken informally to people in the National Kidney Foundation, the Renal Physicians Association, and there has been some interest in pursuing these discussions. These are our suggestions and our testimony for beginning to get a hold on quality of care.

We are not trying to suggest that medical care should be regulated or legislated. We are trying to get the people involved agreeing to protecting all of their own interests.

[The following was subsequently received:]

NATIONAL ASSOCIATION OF PATIENTS ON
HEMODIALYSIS AND TRANSPLANTATION, INC.,
New York, N.Y., May 7, 1982.

JOHN J. SALMON,
Chief Counsel, Committee on Ways and Means, U.S. House of Representatives, Washington, D.C.

DEAR MR. SALMON: I am pleased to enclose the corrected transcript of the testimony presented by NAPHT at the Subcommittee on Oversight hearing on the End Stage Renal Disease program on April 22, 1982. On page 38 of the transcript, Congressman Rangel asked us for information on evaluation of quality of care.

NAPHT does not have a final answer to this question, but is deeply concerned about the lack of data and the inadequate quality assurance mechanisms now in place. On page 5 of our formal comments (in the form initially submitted to the Subcommittee—additional copy enclosed), we addressed the quality of care issue. With both the issue of quality of care and cost of treatment, the primary need is for more data.

We would reiterate our previously stated concern that the current data and quality system in place, the ESRD Networks, should not be eliminated until and unless another and better system is in place.

Please share this information with Congressman Rangel. If further information is needed, please let me know.

Sincerely,

MARGARET DIENER,
Executive Director.

Chairman RANGEL. But when doctors and providers tell your association that they have reached a decision that the proposed reimbursement rates will force them to close, you do not have time to evaluate that. You have to immediately come to their support, do you not?

Ms. DIENER. We base our assessment on what HCFA said in the Federal Register. Yes, we have been told by providers they cannot stay in business. But we have no way of evaluating that. We assume HCFA does, and if they say 46 percent of hospitals and 28 percent of independent facilities have costs above the new proposed rate, that is where our concern comes from.

Chairman RANGEL. How do patients, who really have no idea what the best modality is for them—they want to live and stay well, and most of them do not care what the process is as long as they have confidence in their doctor. If you tell a company that it can make more money by directing patients toward home dialysis and the person concerned with reimbursement is concerned with money, how does the doctor fit into that?

You have a patient and you are on salary and you are not going to make any more money no matter what happens. And the person who hired you now looks and finds out that, assuming HCFA is right—and I hope nothing I say infers that I do believe they are right. [Laughter.]

But assuming they did work out something where it would be more profitable to provide training, physical, psychological, and better health care at home, and the bookkeeper says, my God, we are in the wrong business, we should not be doing this here, we should be sending them home, how does the doctor fit into that at all?

Dr. RICHARD M. FREEMAN. It is a very complex question, and you are talking to a physician in whose State 30 to 40 percent of patients get trained for home dialysis now.

But what you are saying is, if the situation told me more money would be made for home dialysis in my State, I would have to look the administrator in the eye and say: Well, you know, for the past 10 years we have pushed toward home dialysis, and we may have a few additonal patients for whom this is appropriate, but not many, and this is not going to be an area where money will be made.

Now, if you go to another place in which this potential has not been realized, I can conceive where that might be a successful venture. But I cannot predict this. To assume that all of our motivations are related to the economic aspects is not true.

As I said before, doctors have been trained how to diagnose illnesses and save lives. We have not been trained to be economists. That is a recent issue.

Chairman RANGEL. I am not talking about doctors. I did not make my question clear. I am assuming the doctor is an employee of a nondoctor.

Dr. RICHARD M. FREEMAN. All right, the doctor is an employee of the nondoctor.

Chairman RANGEL. The doctor's employer is a corporation with stockholders.

Dr. RICHARD M. FREEMAN. I see. I do not know how to answer that question.

Mr. NEWMANN. I might comment from a patient's point of view. One of the dangers of overstressing economic incentives in this whole area is the destruction of the doctor-patient relationship. One would hope that the mode of treatment and the location of treatment would be determined primarily by medical and appropriate psychological, personal and environmental grounds.

If patients are to be able to maintain a trust in their doctors to assist them in deciding where the best place for treatment is, the economic incentives for a corporation owning a facility must not override this important doctor-patient relationship.

Chairman RANGEL. Mr. Newmann, I could not agree with you more. But you are here trying to improve access, quality of care, and to make certain that arbitrary reimbursement rates are not set, right? That would damage the quality and access. There is nothing I would like better than to perfect the doctor-patient relationship. But I did not create these chains of dialysis centers throughout the country, and you as a patient cannot see the chairman of the board at the center where you are being dialysed.

It is not my fault. I am just asking. If the rate change comes in and your doctor is not able to make decisions—and I know the doctor has a code of ethics and everything else, but he has a job.

Mr. NEWMANN. Well, as came up in the national conference in the beginning of March, there were some who speculated that if the rates are not appropriate and people were being forced home inappropriately, unfortunately the answer may end up in some lawsuits as a result of patient deaths.

Chairman RANGEL. Let me inerrupt. First of all, I want all of the help I can get from patients and doctors that they are not forced to take home dialysis under conditions which for health reasons are not practical, health including physical as well as psychological. I do not want to interfere with what any doctor decides. If they make mistakes they have enough problems without having legislative oversight, all right.

I am concerned about creating incentives where it is practical perhaps to have home care, to have hospital care, to have site care. But nondoctors are making that decision, or it appears that the reimbursement would concern nonmedical people.

Mr. **Newmann**. If you are looking for incentives for patients, I do not know whether Margaret——

Chairman **Rangel**. Not patients, I guess. It is for patients to not be concerned about the costs, for patients to be confident that their doctor is giving them the best advice and treatment that is available, and that the doctor is not coerced, in order to make certain that the company, to be able to pay an adequate return for their investment to stockholders is not telling the doctor, you did not send enough people home.

You mentioned something about 40 to 50 percent of patients going home under CAPD.

Dr. **Richard** M. **Freeman**. What I mentioned is, it appears that of the new patients who entered dialysis somewhere between 40 and 50 percent are now going home for home dialysis, including home hemo as well as peritoneal dialysis.

Chairman **Rangel**. What percentage is peritoneal dialysis?

Dr. **Richard** M. **Freeman**. I do not know what the breakdown is. I just know the total numerator and denominator. I just know there is a move toward home dialysis, which was not present 3 or 4 years ago, based upon HCFA's recent figures.

Chairman **Rangel**. OK. Well, we are going to have a long day, and I hope for the record that, Mr. Newmann, you will be able to tell me, which has nothing to do with the present hearing, how patients would like to have the services available evaluated and how you can assist me in asking the administration to evaluate the costs of those services without getting involved in the doctor-patient relationship.

And you, doctor, I hope will be able to send some information to the committee as to when an administrator decides he is going to use the reimbursement rate to influence medical decisions, where the American Medical Association stands on that, without doing violence to the private sector and a free marketplace.

Dr. **Richard** M. **Freeman**. Gotcha.

Chairman **Rangel**. And we will work with the kids later.

Thank you very much.

Are there other questions from staff?

Mr. **Martin**. Mr. Chairman, may I ask a question of Mr. Newmann?

Chairman **Rangel**. I am terribly sorry. I apologize.

Mr. **Martin**. I have a question of Mr. Newmann. I arrived late.

Mr. Newmann, you have asserted that there has been a high degree of cost in the end-stage renal disease program, and, there have been studies showing the cost per patient has declined in real dollars, if not in current dollars. There seems to be an apparent contradiction to that in your first recommendation where you recommend a specific adjustment for inflation in the calculations.

I wonder if you could expand on that a little bit? Why you would need to make an adjustment for inflation? If you have good data showing the real cost has declined, or has not risen as fast as inflation, then why would you want to raise the guidelines as fast as inflation? Apparently there is no need to if the first statement is correct.

Mr. **Newmann**. Currently the independent facilities have a reimbursement rate of $138, 80 percent of which medicare pays for. The proposed regulations are suggesting an average rate of $128. If you do the arithmetic, that is even incorrect. It gets down to about $124 on the average when you apply the methodology HCFA has proposed.

Our suggestion is, given the success of the program, given the fact that the increase in costs is due to increased numbers, not increased real costs per patient, the inflationary element involved in current costs in 1982 we suspect is not reflected in the methodology and rates proposed based upon 1977, 1978, and 1979 data.

At the very least, it seems reasonable to include that, so that if your estimates are accurate with what is going on in the economy this would not involve an increased per patient per year cost.

Mr. **Martin**. I understand your point about the number of patients increasing, and certainly that should be a factor. But you address the inflation rate. Presumably, you are wanting a Consumer Price Index adjustment.

Ms. **Diener**. Congressman Martin, there have been a number of technological changes in the past 10 years. When our organization started in 1969, patients were normally dialyzed 12 to 15 hours a day. It is now down to about 4 hours per session.

The concern is, assuming there will be that kind of technological advance in the future, it may or may not occur, but to make that kind of assumption and simply say that inflation is not a factor——

Mr. **Martin**. Has anything happened since 1977?

Ms. **Diener**. I would let other technical people address that.

Mr. **Martin**. Are we doing everything today as we did in 1977? Because their claim is that the data base from 1977 to 1979 should be adjusted for inflation. If we have had some improvements in that time, then perhaps not?

Dr. **Richard M. Freeman**. I think the intimation is, why use old data to determine reimbursement in 1982?

Mr. **Martin**. Do you have current data?

Dr. **Richard M. Freeman**. No. That is the point. Why use the data from 1979 if it is available from 1980 to 1982.

Mr. **Martin**. Is it available?

Dr. **Richard M. Freeman**. It certainly should be. We send a lot of it in.

Mr. **Martin**. If it is available, then why make a point about adjusting for inflation? Why not just make a point about using up to date data.

Dr. **Richard M. Freeman**. That would be fine.

Mr. **Newmann**. The reason the point was made about adjusting for inflation was, we are often told by the data for current years is not processed. I think all of the centers are sending it in, but there have been problems with their management information system.

Whatever data is used, we all agree should be relevant to costs in 1982.

Mr. **Martin**: The reasons that caught my eye, I am sure you are aware there are some other discussions going on up here on the Hill regarding the extent to which we have adjusted so many things to the Consumer Price Index that the adjustment has meant that those programs have risen in cost faster than other indicators, faster than the devaluation of the currency, faster than the increase in wages of those who have to pay taxes to support all of these programs.

And some attempt is being made to tighten down on the use of easy cost-of-living adjustments.

Mr. **Newmann**. In this case, the proposed rule suggests a decrease of close to 10 percent, if you work out the methodology.

Mr. **Martin**. I would feel a lot better about going on the basis of the more recent data you have.

Mr. **Newmann**. So would we.

Mr. **Martin**. And still trying to encourage the optimum use of home dialysis and whatever mode would encourage that development, because that has been a contributing factor, is that not so, in the decreasing cost per patient?

Dr. **Richard** M. **Freeman**. There are many factors. That is one of many.

Mr. **Martin**. Has it been a major one?

Dr. **Richard** M. **Freeman**. I think it has been a major one. But there are other efficiencies which have helped, too. Many factors are involved.

Mr. **Martin**. Thank you, Mr. Chairman.

Chairman **Rangel**. Thank you.

This has been a good panel. I hope your schedules will allow you to wait until the administration finishes their testimony.

The next panel is: Dr. John Capelli, chief of staff of Our Lady of Lourdes Hospital, Camden, N.J., on behalf of Catholic Hospital Association; and my friend and colleague, Congressman Norman Mineta is with us and will be introducing the next panelist; and Dr. Ann Thompson, director of division of renal disease, George Washington University Hospital; and Dr. Alan Gruskin, St. Christopher's Hospital for Children.

And the Chair recognizes Congressman Mineta.

Mr. **Mineta**. Mr. Chairman and members of the committee, I really do appreciate your indulgence——

Chairman **Rangel**. I am terribly sorry. Robert Fortner, did I call Dr. Fortner, director of El Camino, on behalf of North California Hospital Dialysis Procedures? Very well.

STATEMENT OF HON. NORMAN Y. MINETA, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. **Mineta**. Prior to my service here, I was a member of a hospital board of trustees for a number of years, and so I would like to at this time take the opportunity to introduce to you a friend, a person who has been the medical director of the El Camino Dialysis Services of Mountain View, North California, Dr. Robert W. Fortner.

Dr. Fortner is accompanied here today at the committee hearings by Mr. Donald Simmons, the manager of the El Camino facility. He is also here in his capacity as immediate past president of the National Renal Administrators Association.

The El Camino center is operated by the El Camino Hospital District. The center has a multifaceted program, including services to 64 patients at the facility and to 70 home patients. This mix of alternatives allows the physicians and the patients to jointly develop a program of treatment that best meets the patient's needs at the lowest possible cost.

The center is one of the home dialysis training programs in our State. In fact, the first patient was trained by the center for home treatment in 1967, a patient whom I am happy to say is still alive 15 years later. In that period, the center has trained more than 300 home patients.

Now, I have been a great admirer of the El Camino program for a number of years. Dr. Fortner and Mr. Simmons have done an excellent job in developing a flexible program able to respond to each patient's unique needs. We all share, I believe, a support for the general principle of providing medical care at the lowest reasonable cost. We also share a sense that home dialysis is an important option that should be made available to renal patients.

How best to structure a set of Federal rules and reimbursement practices to encourage such treatment is of course a complex and difficult question. I am sure as the committee continues its consideration of these difficult matters, Dr. Fortner's and Mr. Simmons' background and experience will be of great help to all of you.

Again, Mr. Chairman, I appreciate this opportunity to introduce Dr. Fortner and Mr. Simmons. And I am quite sure their background and experience will be helpful to all of you, as it has been to me in the past.

Chairman **RANGEL**. The Chair and the committee would like to thank you for your introduction and your interest in this matter, and we will feel free to go to the Budget Committee on this. [Laughter.]

Mr. **MINETA**. That is right.

Chairman **RANGEL**. Dr. Capelli.

STATEMENT OF JOHN P. CAPELLI, M.D., CHIEF OF STAFF, OUR LADY OF LOURDES HOSPITAL, CAMDEN, N.J., ON BEHALF OF THE CATHOLIC HEALTH ASSOCIATION

Dr. **CAPELLI**. Thank you, Mr. Chairman, Mr. Pickle.

I am Dr. John Capelli, chief of staff and director of nephrology and transplantations at Our Lady of Lourdes Hospital, Camden, N.J. Today I speak for the Catholic Health Association with regard to the medicare end-stage renal disease program.

We support the concept of the dual composite rate as an incentive reimbursement system and as a stimulus to improve less costly levels of home dialysis care. However, the CHA is deeply disturbed over the basic thrust of these rules as proposed by HCFA and their effects upon patients, facilities, and physicians in the ESRD program.

In establishing a dual composite rate for ESRD services, Congress intended to promote a recognizable distinction in costs for hospitals and freestanding facilities. The CHA commends Congress for its appreciation of the legitimate cost differential between hospital-based and independent ESRD facilities.

Unfortunately, there was an equally clear intention by HCFA not to create a dual reimbursement rate for each type of provider, and further, there was to be an ultimate intent to phase out whatever separation in rates, as was expressed in the decision memorandum to Secretary Schweiker. This expressed goal by HCFA has very serious consequences.

HCFA obviously feels that hospital-based facilities are unjustifiably costly and inefficient. However, hospital-based facilities have higher costs for several reasons, one of which is their average smaller size. Studies have shown that there is an inverse relationship between unit costs and facility treatments, the latter obviously being a function of unit size.

In addition, hospitals by virtue of their need to support the acutely ill inpatient, will always require higher indirect cost allocation than a free-standing facility.

Second, the unstable dialysis patient and the dialysis patient with an acute illness needs a greater skill and level of care, skills which can only be achieved by a health care team that provides a significant amount of ongoing dialysis care to ongoing patients.

Third, hospital-based programs have the best record in home dialysis, and in a recently published study, home training costs were $143 higher in for-profit facilities than in the not-for-profit, primarily hospital-based facilities.

Thus, HCFA, by placing 46 percent of the hospital providers at risk by very significant reductions in the proposed reimbursement rates, jeopardizes the level of services in those institutions needed to care for the sickest patients, those which provide the highest level of home dialysis, and those which are offering home training programs most economically.

For any agency to set rates properly for providers of service, we feel two criteria are critical: First, the methodology must be clearly set forth and equally applied; and second, up-to-date cost data must be collected regularly in a uniform accounting fashion.

HCFA did not meet these two basic criteria. Cost data was applied which was not truly representative of either group, and dialysis rates were selected which impacted most adversely on hospital providers.

The CHA believes that additional significant defects exist with the proposed methodology. There was no provision for annual cost data collection and publication of new rates. There was no provision to account properly for the true cost of home training programs. There was no provision to permit for a graduated phase-in period, allowing providers to adjust to potential reductions in reimbursements.

There was no provision to cost-account home aides in the performance of home dialysis. There was no provision for the cost of home dialysis equipment. There was no provision to permit flexibility in the area wage adjustments, resulting in arbitrary increases or decreases in rates unrelated to true costs. There was no provision for inflationary adjustments from a base year to a year of implementation.

There was no provision to allow for legitimate cost differences under the exception process, because of a lack of standards against which those differences could be compared.

Consequently, the Catholic Health Association would recommend the following: In regard to facility reimbursement, there should be a provision for HCFA to collect updated cost data utilizing a uniform cost accounting system from all providers. There should be a provision to update cost data and ratesetting on an annual basis. There should be a provision for inflationary adjustments to occur from the determination of the base year for ratesetting to the actual year of implementation.

There should be a mandatory provision that the ratesetting methodology be set forth in proposed rulemaking without any publication of stated rates. The methodology should be applied in a manner which truly reflects the costs of independent programs and hospital programs. It should be reflective of overall national home dialysis rates and be permitted to allow a phase-in period of approximately 2 years for providers and intermediaries to adjust to the new rates and the new system.

The exception process should include provisions to account for facilities which can validly demonstrate higher costs by making available cost data for comparison.

Any application of the labor wage indices should take into consideration preexisting cost levels such that excess increases or decreases in reimbursement do not occur arbitrarily. The costs accrued for home aides should be included in the calculation of allowable costs for home dialysis. And the 100-percent equipment reimbursement provision as defined under Public Law 95-292 must be permitted to remain in force.

In regard to physician reimbursement, we feel any changes in physician reimbursement should follow all statutory provisions and congressionally mandated studies. Any changes in physician reimbursement should take into account effects on total patient costs, the quality of care, the availability of physicians to meet ongoing patient needs, including preventive care, and the effects on potential consumption of more costly medical services, such as increased hospitalizations.

And lastly, we feel there should be a provision for the creation of a special service or branch within the HCFA organization composed of a knowledgeable staff to administer the ESRD program.

The CHA believes a properly developed dual composite rate can be established and implemented which will improve home dialysis and effect cost savings without impacting on quality of care. However, the regulations as presently proposed by HCFA will not achieve that goal.

Thank you, Mr. Chairman, for the opportunity to express the views of the Catholic Health Association on the medicare ESRD program.

[The prepared statement follows:]

STATEMENT OF THE CATHOLIC HEALTH ASSOCIATION OF THE UNITED STATES, PRESENTED BY JOHN P. CAPELLI, M.D., DIRECTOR OF NEPHROLOGY, CHIEF OF STAFF, OUR LADY OF LOURDES HOSPITAL, CAMDEN, N.J.

MR. CHAIRMAN, I AM DOCTOR JOHN CAPELLI, CHIEF OF STAFF OF OUR LADY OF LOURDES HOSPITAL, CAMDEN, NEW JERSEY AND DIRECTOR OF NEPHROLOGY AND TRANSPLANTATIONS AT THAT FACILITY. TODAY, I AM THE SPOKESMAN FOR THE CATHOLIC HEALTH ASSOCIATION WITH REGARD TO ITS POSITION ON THE MEDICARE END-STAGE RENAL DISEASE PROGRAM.

THE ASSOCIATION REPRESENTS 640 CATHOLIC HOSPITALS IN THE UNITED STATES, OVER ONE-THIRD OF WHICH PROVIDE ESRD SERVICES, INPATIENT, OUT-PATIENT AND/OR HOME-BASED DIALYSIS. ON BEHALF OF THE ASSOCIATION, I WISH TO THANK THE OVERSIGHT SUBCOMMITTEE OF THE COMMITTEE ON WAYS AND MEANS FOR THE OPPORTUNITY TO PRESENT OUR VIEWS ON THE HEALTH CARE FINANCING ADMINISTRATION'S PROPOSED RULEMAKING ESTABLISHING A COMPOSITE, PROSPECTIVE, INCENTIVE REIMBURSEMENT RATE FOR OUT-PATIENT AND HOME DIALYSIS SERVICES.

UNIQUENESS OF ESRD PROGRAM

THE ESRD PROGRAM HAS CONTINUALLY ATTRACTED THE ATTENTION OF CONGRESS AND THE DEPARTMENT OF HHS BECAUSE OF ITS GROWTH IN EXPENDITURES SINCE 1973. BECAUSE THE PROGRAM NOW SERVICES 68,200 BENEFICIARIES AT A MEDICARE COST OF APPROXIMATELY $1.2 BILLION, AN AMOUNT REPORTEDLY REPRESENTING 3.8 PERCENT OF THE TOTAL MEDICARE BENEFIT PAYMENT, REPEATED CALLS ARE HEARD FOR WAYS TO CONTAIN THE COST OF THE PROGRAM, OR PERHAPS REDUCE ITS COST. TO SOME EXTENT, THE PROGRAM SUFFERS FROM THE GLARE OF ISOLATION BECAUSE OF ITS UNIQUENESS. IF MEDICARE COULD ISOLATE ITS COSTS FOR OTHER CATEGORICAL DISEASES SUCH AS CANCER OR CORONARY-ARTERY

DISEASE IN SUCH A WAY AS TO COMPARE EXPENDITURES FOR THE ESRD SERVICE, PERHAPS THE EFFICIENCIES AND ECONOMIES IN THE ESRD PROGRAM WOULD BE MORE EVIDENT, AND EVEN MORESO, APPRECIATED.

NOTICE OF PROPOSED RULEMAKING ON INCENTIVE REIMBURSEMENT

THE PROPOSED RULEMAKING OF FEBRUARY 12, 1982 ATTEMPTS TO IMPLEMENT THE PROVISIONS OF P.L. 97-35 WITH REGARD TO A PROSPECTIVE INCENTIVE REIMBURSEMENT RATE FOR FACILITIES AND AN ALTERATION IN THE REIMBURSEMENT FOR RENAL PHYSICIANS. ALTHOUGH WE DO NOT FEEL THAT HCFA INTENDED TO AFFECT EITHER THE AVAILABILITY OR THE QUALITY OF CARE FOR PATIENTS, THE PROPOSED METHODOLOGY AND REIMBURSEMENT RATES COULD RESULT IN PRECISELY THOSE EFFECTS.

IN ESTABLISHING A DUAL, COMPOSITE RATE FOR ESRD SERVICES, CONGRESS CLEARLY INTENDED TO PROMOTE A RECOGNIZABLE DISTINCTION IN COSTS FOR HOSPITALS AND FREE-STANDING FACILITIES. THE CATHOLIC HEALTH ASSOCIATION COMMENDS CONGRESS FOR ITS APPRECIATION OF THE LEGITIMATE COST DIFFERENTIAL BETWEEN HOSPITAL-BASED AND INDEPENDENT ESRD FACILITIES. UNFORTUNATELY, THERE WAS AN EQUALLY CLEAR INTENTION BY HCFA NOT TO CREATE A DUAL REIMBURSEMENT RATE FOR EACH TYPE OF PROVIDER, AND FURTHER, THERE WAS AN ULTIMATE INTENT TO "PHASE IT (I.E., SEPARATE RATES) OUT ALTOGETHER", AS EXPRESSED IN ITS DECISION MEMORANDUM TO SECRETARY SCHWEIKER.

IN ADDITION TO THIS NOT SO SUBTLE ATTEMPT BY HCFA TO CIRCUMVENT THE INTENT OF CONGRESS, THIS EXPRESSED GOAL OF HCFA COULD HAVE VERY SERIOUS CONSEQUENCES. HCFA OBVIOUSLY FEELS

HOSPITAL-BASED FACILITIES ARE UNJUSTIFIABLY COSTLY AND INEFFICIENT. HOSPITAL-BASED FACILITIES DO HAVE HIGHER COSTS BECAUSE OF SEVERAL FACTORS, ONE OF WHICH IS THEIR AVERAGE SIZE. THE AVERAGE HOSPITAL UNIT IS UNDER 10 BEDS; THE AVERAGE INDEPENDENT UNIT IS 14 BEDS. STUDIES BY THE URBAN INSTITUTE HAVE SHOWN THAT A RELATIONSHIP EXISTS BETWEEN UNIT COST AND FACILITY TREATMENTS, THE LATTER OBVIOUSLY A FUNCTION OF UNIT SIZE. THE HIGHEST COST FACILITIES WERE THOSE WITH LESS THAN 5,000 TREATMENTS PER YEAR ($160), WHILE FACILITIES WITH BETWEEN 10,000 AND 20,000 DIALYSES HAD THE LOWEST COST ($147).

HOSPITALS, BY VIRTUE OF THEIR NEED TO SUPPORT THE ACUTELY ILL INPATIENT, WILL ALWAYS REQUIRE A HIGHER INDIRECT COST ALLOCATION THAN A FREE-STANDING FACILITY. STUDIES HAVE ALSO SHOWN THAT HOSPITAL-BASED FACILITIES HAVE HIGHER UNIT COSTS BECAUSE OF A GREATER SALARY COST FOR STAFF. THE UNSTABLE DIALYSIS PATIENT AND THE DIALYSIS PATIENT WITH AN ACUTE INTER-CURRENT ILLNESS NEEDS A GREATER SKILL AND HIGHER LEVEL OF CARE. SUCH SKILLS CAN ONLY BE ACHIEVED BY A HEALTH CARE TEAM THAT PROVIDES A SIGNIFICANT AMOUNT OF ON-GOING DIALYSIS CARE TO A VARIETY OF PATIENTS. THUS, HOSPITAL-BASED UNITS MUST BE PERMITTED TO CONTINUE PROVIDING DIALYSIS CARE TO BOTH TYPES OF PATIENTS IF QUALITY CARE IS GOING TO BE AVAILABLE WHEN THE COMPLICATED PATIENT PRESENTS. FINALLY, HOSPITAL-BASED PROGRAMS HAVE THE BEST RECORD IN HOME DIALYSIS, 23.5% VERSUS 10.5% FOR INDEPENDENT FACILITIES. IT IS ALSO NOTEWORTHY TO POINT OUT

THAT IN A RECENTLY COMPLETED HCFA FINANCED STUDY BY THE ORKAND CORPORATION, HOME-TRAINING COSTS WERE $143.02 HIGHER IN THE FOR-PROFIT FACILITIES THAN IN THE NOT-FOR-PROFIT FACILITIES.

THUS, CITING HCFA'S OWN FIGURES, THE PROPOSED REGULATIONS WOULD PLACE 46% OF THE HOSPITAL-BASED PROVIDERS AT RISK BY VERY SIGNIFICANT REDUCTIONS IN THEIR REIMBURSEMENT RATES. BY THIS ACTION, HCFA JEOPARDIZES THE DELIVERY OF SERVICES IN THOSE INSTITUTIONS NEEDED TO CARE FOR THE SICKEST PATIENTS, THOSE INSTITUTIONS WHICH ARE PROVIDING THE HIGHEST LEVEL OF HOME DIALYSIS AND THOSE INSTITUTIONS WHICH ARE OFFERING HOME-TRAINING PROGRAMS MOST ECONOMICALLY.

THE INADEQUACY OF THE PROPOSED METHODOLOGY AND RATE-SETTING

FOR ANY AGENCY TO SET RATES PROPERLY FOR PROVIDERS OF SERVICE, TWO CRITERIA ARE CRITICAL TO A FAIR AND EQUITABLE SYSTEM:

1. THE METHODOLOGY MUST BE CLEARLY SET FORTH, UNDERSTOOD BY THE PROVIDERS, AND EQUALLY APPLIED; AND,
2. UP-TO-DATE COST DATA MUST BE COLLECTED REGULARLY IN A UNIFORM ACCOUNTING FASHION, AND THEN APPLIED TO THE FORMULA RULE.

UNFORTUNATELY, IN ITS ISSUANCE OF ESRD REGULATIONS, HCFA HAS NOT MET THESE TWO BASIC CRITERIA. IN THE FIRST INSTANCE, THE METHODOLOGIC FORMULA DID NOT FOLLOW THE INTENT, NOR THE MANDATE, OF CONGRESS IN DEVELOPING SEPARATE RATES BASED UPON THE RECOGNIZABLE COSTS OF HOSPITAL PROVIDER GROUPS AND THE RECOGNIZABLE

COSTS OF INDEPENDENT PROVIDER GROUPS. THE MEDIAN COSTS FOR ALL FACILITIES WERE APPLIED IN EACH RATE DERIVATION RATHER THAN MEDIAN COSTS FOR HOSPITALS, AND THE MEDIAN COSTS FOR INDEPENDENTS AS ONE WOULD HAVE EXPECTED FROM THE PROVISIONS OF THE STATUTE. SECONDLY, THE WEIGHTING OF THE DATA BY THE PERCENTAGES FOR HOME AND IN-CENTER DIALYSIS WAS DONE BY USING THE HOSPITALS' PERCENTAGE (23.5%) IN THE DERIVATION OF THEIR RATES, AND THE INDEPENDENTS' PERCENTAGE (10.5%) IN THE DERIVATION OF THEIR RATES, RESULTING IN A FURTHER SKEWING OF THE COST FIGURES DOWNWARD FOR HOSPITAL PROGRAMS. IT WAS CLEAR WHAT THE INTENT OF CONGRESS WAS ON THIS ITEM BECAUSE THE HOUSE WAYS AND MEANS COMMITTEE REPORT SPECIFICALLY IDENTIFIED AND APPLIED THE NATIONAL RATES IN THE DEVELOPMENT OF THE COMPOSITE RATE CONCEPT. EVEN WITH REGARD TO THE OVERHEAD COSTS, THERE WAS A DISTORTION OF THE HOSPITALS' TRUE OVERHEAD COSTS BY A REDUCTION OF NEARLY $5 PER UNIT COST BEFORE APPLICATION INTO THE FORMULA. THE ENTIRE PROCESS USED BY HCFA REVEALED AN INCONSISTENT APPLICATION OF DATA TO CLOSE THE DIFFERENCE BETWEEN THE TWO PROVIDER GROUPS TO VIRTUALLY ZERO.

IN REGARD TO THE SECOND CRITERION IN THE RATE-SETTING PROCESS, HCFA CLEARLY ADMITS IT DOES NOT HAVE SOLID UP-TO-DATE DATA. FURTHER, SINCE THE DATA IS SPREAD OUT OVER THREE YEARS, 1977-1978-1979, AN INFLATIONARY FACTOR SHOULD HAVE BEEN RECOGNIZED AT THE TIME OF IMPLEMENTATION. THE HCFA HAS FAILED TO ACCOUNT FOR INFLATIONARY CHANGES FROM A BASE YEAR TO AN IMPLEMENTATION YEAR, AND ARBITRARILY SETS IT ASIDE WITH NO

RATIONAL JUSTIFICATION.

FINALLY, HCFA'S ATTEMPT TO COMPENSATE FOR POSSIBLE ERRORS IN ITS COST DATA BASE, AND ITS METHODOLOGY BY FINALIZING THE FINAL RATES FOR HOSPITAL-BASED PROGRAMS WITH AN ADJUSTMENT FACTOR OF 1.05 HAS NO DERIVED BASIS, IS ADMITTEDLY ARBITRARY, AND PATENTLY INDEFENSIBLE.

THE CATHOLIC HEALTH ASSOCIATION BELIEVES THAT ADDITIONAL SIGNIFICANT DEFECTS EXIST WITH THE PROPOSED METHODOLOGY AS FOLLOWS:

- NO PROVISION FOR ANNUAL COST DATA COLLECTION AND PUBLICATION OF NEW RATES;
- NO PROVISION TO PROPERLY ACCOUNT FOR THE TRUE COSTS OF HOME-TRAINING PROGRAMS (I.E., A $20 ADDITIONAL ALLOWANCE FOR HOME-TRAINING UNIT COST IS WHOLLY INADEQUATE);
- NO PROVISION TO PERMIT A GRADUATED PHASE-IN ALLOWING PROVIDERS TO ADJUST TO POTENTIAL REDUCTIONS IN REIMBURSEMENT;
- NO PROVISION TO COST ACCOUNT HOME AIDES IN THE PERFORMANCE OF HOME DIALYSIS WHEN NEEDED;
- NO PROVISION TO COMPENSATE FOR THE COST OF HOME DIALYSIS EQUIPMENT;
- NO PROVISION TO PERMIT FLEXIBILITY IN THE AREA WAGE ADJUSTMENTS WHICH COULD RESULT IN ARBITRARY INCREASES OR DECREASES IN RATES UNRELATED TO TRUE COSTS.

INADEQUATE EXCEPTIONS PROCESS

THE PROPOSAL SET FORTH BY HCFA FOR GRANTING EXCEPTIONS IN

FOUR SPECIFIC INSTANCES FAILS TO TAKE INTO CONSIDERATION OTHER LEGITIMATE COST DIFFERENCES IN SERVICE. UNLESS HCFA COLLECTS COST DATA ON AN ANNUAL BASIS, NO FACILITY COULD POSSIBLY OBTAIN AN EXCEPTION FOR LEGITIMATE COST DIFFERENCES ABOVE THE SET RATES BECAUSE THERE WOULD BE NO STANDARDS AGAINST WHICH TO COMPARE THOSE DIFFERENCES.

THERE MUST BE AN ESTABLISHED PROCESS TO PROVIDE BOTH HCFA AND THE PROVIDER AN AVENUE OF RECOURSE FOR JUSTIFICATION OF ITS POSITION WHEN DIFFERENCES IN RATE ALLOWANCES OCCUR.

PROPOSED RULEMAKING ON PHYSICIAN REIMBURSEMENT

THE CATHOLIC HEALTH ASSOCIATION RECOMMENDS THAT ANY PROPOSED CHANGES IN PHYSICIAN REIMBURSEMENT BE DEALT WITH IN A SEPARATE PROPOSED RULEMAKING. METHODOLOGY AND RATE-SETTING FOR FACILITIES SHOULD NOT BE COMBINED IN A REGULATION WITH PHYSICIAN FEE REIMBURSEMENT.

FURTHER, THE CHA WOULD RECOMMEND THAT ANY PROPOSED CHANGES IN PHYSICIAN REIMBURSEMENT, AS THAT WITH FACILITY REIMBURSEMENT, TAKE INTO ACCOUNT ITS EFFECT ON TOTAL PROGRAM COSTS, NOT JUST ON PHYSICIAN COSTS. THE IMPACT ON QUALITY PATIENT CARE WITH REGARD TO PHYSICIAN AVAILABILITY AND A CONSUMPTION OF MORE COSTLY MEDICAL RESOURCES SHOULD BE CAREFULLY ANALYZED BEFORE IMPLEMENTING RADICAL REDUCTIONS IN REIMBURSEMENT FOR ANY PROVIDER OF CARE.

SUMMARY

WHILE THE CATHOLIC HEALTH ASSOCIATION IS CONCERNED ABOUT THE COSTS OF THIS PROGRAM, IT HASTENS TO ACKNOWLEDGE THAT A

MAJOR FACTOR IN ITS RISING COSTS IS RELATED TO INCREASED VOLUME. THE ACTUAL COST PER PATIENT HAS NOT INCREASED ANYWHERE NEAR THAT WHICH HAS OCCURRED IN OTHER HEALTH CARE RELATED AREAS.

THE CHA SUPPORTS AND PROMOTES THE CONCEPT OF A SOUND, RATIONAL AND QUALITY HOME DIALYSIS CARE PROGRAM. HOWEVER, SUCH A POLICY CANNOT OCCUR AT THE EXPENSE OF THE IN-CENTER DIALYSIS PATIENT TRULY IN NEED OF THAT CARE.

THE CATHOLIC HEALTH ASSOCIATION BELIEVES THAT A DUAL, COMPOSITE RATE FOR FACILITY REIMBURSEMENT WHICH IS PROPERLY DEVELOPED, EQUITABLY APPLIED, WITH APPROPRIATE ADJUSTMENTS AND PHASE-IN PERIODS, CAN CONSTITUTE AN EFFECTIVE PROSPECTIVE REIMBURSEMENT SYSTEM FOR ESRD SERVICES. HOWEVER, THE PROPOSED REGULATIONS FAIL TO ACHIEVE THE GOALS OF CONGRESS, AND IN DOING SO, WILL CAUSE SERIOUS PROBLEMS FOR PROVIDERS OF DIALYSIS SERVICES, IN PARTICULAR HOSPITAL-BASED PROGRAMS.

RECOMMENDATIONS

THE CATHOLIC HEALTH ASSOCIATION RECOMMENDS THE FOLLOWING ACTIONS BE TAKEN:

FACILITY REIMBURSEMENT:

- THERE SHOULD BE A MANDATORY PROVISION FOR HCFA TO COLLECT UPDATED COST DATA, UTILIZING A UNIFORM COST-ACCOUNTING SYSTEM FOR ALL PROVIDERS BEFORE IMPLEMENTATION OF ANY NEW RATES.

- THERE SHOULD BE A MANDATORY PROVISION FOR HCFA TO UPDATE ITS COST DATA, AND AS A CONSEQUENCE, ITS RATE-SETTING ON AN ANNUAL BASIS.
- THERE SHOULD BE A MANDATORY PROVISION FOR INFLATIONARY ADJUSTMENTS TO OCCUR FROM THE DETERMINATION OF THE BASE YEAR FOR RATE-SETTING TO THE ACTUAL YEAR OF IMPLEMENTATION.
- THERE SHOULD BE A MANDATORY PROVISION THAT THE RATE-SETTING METHODOLOGY BE:
    1. SET FORTH IN PROPOSED RULEMAKING INITIALLY BEFORE ARBITRARILY APPLIED AND WITHOUT PUBLICATION OF ANY STATED RATES;
    2. APPLIED IN A MANNER WHICH TRULY REFLECTS THE COSTS OF INDEPENDENT PROGRAMS AND HOSPITAL PROGRAMS, DERIVED FOR EACH ONE'S RESPECTIVE COST DATA;
    3. REFLECTIVE OF OVERALL (NATIONAL) HOME DIALYSIS RATES, RATHER THAN EACH GROUP'S APPLIED SEPARATELY.
- THERE SHOULD BE CONTINUED CONGRESSIONAL EFFORTS TO ENFORCE THE PROVISIONS AND THE INTENT OF THE DUAL COMPOSITE RATE WITH THE FOLLOWING MODIFICATIONS:
    1. THE COMPOSITE RATE SHOULD SET A LIMIT OF 30%-35% OF WEIGHTING TO BE GIVEN TO HOME DIALYSIS IN ORDER TO PRECLUDE AN UNACCEPTABLE DECLINE IN IN-CENTER DIALYSIS REIMBURSEMENT RATE.
    2. THE COMPOSITE RATE SHOULD PROVIDE FOR A PHASE-IN PERIOD OF 2-3 YEARS TO PERMIT PROVIDERS AND INTERMEDIARIES THE OPPORTUNITY TO ADJUST TO ANY NEW RATE SYSTEM.
    3. THE EXCEPTION PROCESS SHOULD INCLUDE PROVISIONS FOR UNIQUE SITUATIONS, SUCH AS PEDIATRIC UNITS, TRANSPLANT UNITS, AND HOSPITAL UNITS, WHICH SERVE A LARGE PROPORTION OF INPATIENTS (70% OF TREATMENTS

OR GREATER) WITH AN OUT-PATIENT MIX, AND FACILITIES WHICH CAN VALIDLY DEMONSTRATE HIGHER COSTS.

4. ANY APPLICATION OF LABOR WAGE INDICES MUST TAKE INTO CONSIDERATION PRE-EXISTING COST LEVELS SUCH THAT EXCESS INCREASES OR DECREASES IN REIMBURSEMENT DO NOT OCCUR ARBITRARILY.
5. THE COSTS ACCRUED FOR HOME AIDES, WHERE NECESSARY, MUST BE INCLUDED IN ALLOWABLE COSTS FOR CALCULATION FOR HOME DIALYSIS.
6. THE 100% EQUIPMENT REIMBURSEMENT PROVISION AS DEFINED UNDER P.L. 95-292 MUST BE PERMITTED TO REMAIN IN FORCE.

PHYSICIAN REIMBURSEMENT:

- ANY CHANGES IN PHYSICIAN REIMBURSEMENT SHOULD FOLLOW CONGRESSIONALLY MANDATED STANDARDS AND STUDIES.
- ANY CHANGES IN PHYSICIAN REIMBURSEMENT SHOULD TAKE INTO ACCOUNT EFFECTS ON TOTAL PROGRAM COSTS, QUALITY OF CARE, AVAILABILITY OF PHYSICIANS TO MEET ON-GOING PATIENT NEEDS INCLUSIVE OF PREVENTIVE CARE, AND THE EFFECTS ON POTENTIAL CONSUMPTION OF MORE COSTLY MEDICAL SERVICES.

HCFA ORGANIZATION FOR ESRD PROGRAM:

- THERE SHOULD BE A MANDATORY PROVISION FOR THE CREATION OF A SPECIAL SERVICE WITHIN THE HCFA ORGANIZATION COMPOSED OF KNOWLEDGEABLE STAFF TO ADMINISTER THE ESRD PROGRAM.

THANK YOU, MR. CHAIRMAN, FOR THIS OPPORTUNITY TO EXPRESS THE VIEWS OF THE CATHOLIC HEALTH ASSOCIATION ON THE MEDICARE END-STAGE RENAL DISEASE PROGRAM.

Chairman Rangel. Thank you, doctor.

Dr. Fortner.

STATEMENT OF ROBERT FORTNER, M.D., MEDICAL DIRECTOR, EL CAMINO DIALYSIS SERVICES, ON BEHALF OF NORTHERN CALIFORNIA HOSPITAL DIALYSIS PROVIDERS, ACCOMPANIED BY DONALD SIMMONS, MANAGER

Dr. Fortner. Thank you, Mr. Chairman, Mr. Martin.

I am Dr. Robert Fortner, medical director of a hospital dialysis facility in northern California. I am here today representing a total of 17 northern California hospital dialysis facilities. We appreciate the opportunity to voice our concerns regarding the proposed ESRD regulations, as we believe they will have widespread negative impact if implemented as written.

We believe that the regulations do not meet congressional intent in providing realistic reimbursement to hospital dialysis providers through the mechanism of a dual reimbursement system. Congress has recognized the different nature of hospital-based dialysis treatment and the dual system requires recognition of bona fide hospital costs as well as recognizing costs associated with treatment of more complex patients.

For example, in certain areas of northern California, hospital facilities admit complicated patients who were unable to be treated in local independent facilities due to the complex nature of their illnesses. Furthermore, in areas where hospital and independent dialysis facilities are both readily available, physicians tend to admit their most complicated cases to the hospital outpatient facilities.

This was corroborated in a study of northern California facilities in 1979 which revealed that 82 percent of the most labor intensive patients were in hospital outpatient units. In addition to these preferential admissions, HCFA data reveals a higher home training rate in hospitals. The hospital outpatient population is thus concentrated into a more complex, labor intensive group by these preferential admissions and by the transfer of the hospital's most stable patients into the home.

HCFA is proposing a de facto single rate system which penalizes hospital dialysis providers and is not consistent with congressional intent. This de facto single rate system is based on a faulty methodology and uses data which is old, unsubstantiated and not consistent with current cost experiences. The audit data was hastily collected, arbitrarily adjusted, and in many cases derived only from reporting forms rather than actual audits.

HCFA acknowledges that it does not know whether as many patients of high cost facilities actually require as high a level of care as indicated by the costs. However, assumptions are made as though this possibility did not exist. Consequently, HCFA proposes severe and abrupt reductions in hospital reimbursement by deriving reimbursement rates that fail to realistically account for hospital costs.

HCFA's proposed methodology derives patient allowances from the universe of providers rather than from hospitals alone. In determination of the labor and overhead differentials for hospitals, HCFA calculations result in inadequate reimbursement for hospitals and rewards independents with a $62 million windfall.

We believe that hospital labor costs can be reduced in many areas. However, we believe the labor cost allowance per dialysis in hospital facilities should be reimbursed at the median cost of hospitals alone and that the overhead differential is a valid hospital indicator and should be reimbursed as such.

We believe a dual rate reimbursement system which allows for realistic reimbursement of hospital dialysis treatments will avoid serious disruptions in service in a highly complex and vulnerable group of patients. We recommend this system be phased in over 1 to 2 years.

Our concern over reimbursement rate reductions is closely tied to our concern over the vague and imprecise exceptions process.

The proposed regulations delineate categories under which a facility might qualify for an exception, but clearly defined criteria are absent. For example, the regulations require facilities to compare their atypical patient mix to other facilities with a similar atypical mix. Data for making such comparisons is nonexistent and it is unlikely that another "similar" facility could be identified in this diverse system. Clearly an unreasonable burden.

We believe that significant regional differences exist in this highly diverse and complex treatment arena. We also believe that the complex and poorly described process of physician choice of modality and patient choice of modality, interrelating with medical complications, facility admission criteria and available treatment resources combine to create these differences.

It is vital that all facilities have a clear understanding of this exceptions procedure in order to prevent unnecessary disruptions in service. We urge a careful definition of criteria utilizing an accepted common data base for decisionmaking in this crucial area.

As previously noted, hospitals have home trained 75 percent of patients currently using this treatment location. We contend that the above mentioned penalties on hospital providers and the proposed changes in the home dialysis regulations will conspire to reduce, not enhance, the use of home dialysis.

Inherent with congressional intent is the belief that increased use of home dialysis will reduce medicare ESRD costs. Furthermore, the composite rate is intended to stimulate home dialysis via the facility's ability to retain excess revenues. In appears likely that many hospital dialysis facilities in northern California, and perhaps other States, may be forced into significant alterations in their delivery of services under the proposed reimbursement rates.

Facility closure is one possible alternative. This will reduce the availability of home training services. Further, the elimination of the 100-percent equipment reimbursement provision will increase the cost to facilities providing home dialysis services. Hospital capital resources are scarce and declining. This disincentive, elimination of 100-percent equipment reimbursement for facilities, is coupled to a patient disincentive—an increase in coinsurance costs.

The lower coinsurance costs associated with home dialysis have been the only home dialysis incentive for patients. We believe this 100 percent reimbursement option should be retained and the composite rate adjusted accordingly to allow for continuing equipment

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purchases by the HCFA. Other patient-oriented incentives should be explored as well.

The continued inadequate reimbursement for home training activities is another major disincentive. Facility financial losses in patient training require 6 to 12 months of home support activities for recovery. We suggest development of a flexible reimbursement method, such as a lump sum payment, that allows for interfacility differences and possibly serves as a facility incentive.

The retention of the direct billion option for patients will increase the cost of dialysis. This elective allows patients to bill directly for supplies and equipment and ignores the benefits of facility cost controls, volume purchases, et cetera. It also circumvents the composite rate incentive for the facility as facility payments will be limited to "support" activities. We propose that facilities, not patients, be given this option.

We urge careful reconsideration of the home dialysis regulations with an aim to developing bona fide incentives and elimination of major disincentives.

Finally, we are gravely concerned with patient well being. Proposed reimbursement cuts are taking priority over quality of care issues. HCFA's acknowledged poor data has not prevented proposals aimed at cost savings. These proposals will take place in a system virtually devoid of quality controls. Administrative support for quality assurance has not been clearly stated.

Quality of care changes can only be assessed by adequate data developed over considerable time. We urge a systemwide assessment of quality which must be done concurrently with the rate reductions as the potential adverse consequences may not be detectable for several years.

In summary, we urge a realistic dual rate system which promotes efficiencies without compromising access to care nor the quality of that care.

Thank you.

[The prepared statement follows:]

STATEMENT OF NORTHERN CALIFORNIA HOSPITAL DIALYSIS PROVIDERS PRESENTED BY ROBERT W. FORTNER, M.D., REPRESENTING: EL CAMINO DIALYSIS SERVICES, FRESNO COMMUNITY HOSPITAL, MILLS MEMORIAL HOSPITAL, MOUNT ZION HOSPITAL, MT. DIABLO HOSPITAL, NATIVIDAD MEDICAL CENTER, PRESBYTERIAN HOSPITAL, PROVIDENCE HOSPITAL, QUEEN OF THE VALLEY HOSPITAL, RALPH K. DAVIES MEDICAL CENTER, SANTA CLARA VALLEY MEDICAL CENTER, STANFORD UNIVERSITY HEMODIALYSIS CENTER, SUTTER GENERAL HOSPITAL, SUTTER MEMORIAL HOSPITAL, UNIVERSITY OF CALIFORNIA RENAL CENTER, WASHINGTON HOSPITAL, AND WASHOE MEDICAL CENTER

Mr. Chairman, I am Robert W. Fortner, M.D., the Medical Director of a hospital dialysis facility in Northern California and I am here today representing a total of 17 Northern California hospital dialysis facilities. We appreciate the opportunity to voice our concerns regarding the proposed ESRD regulations as we believe they will have a wide spread negative impact if implemented as written.

We believe that the regulations do not meet Congressional intent in providing realistic reimbursement to hospital dialysis providers through the mechanism of a dual reimbursement system. Congress has recognized the different nature of hospital-based dialysis treatment and the dual system requires recognition of bona fide hospital costs as well as recognizing costs associated with treatment of more complex patients.

For example, in certain areas of Northern California, hospital facilities admit complicated patients who were unable to be treated in local independent facilities due to the complex nature of their illnesses. Furthermore, in areas where hospital and independent dialysis facilities are both readily available, physicians tend to admit their most complicated cases to the hospital outpatient facilities. This was corroborated in a study of Northern California facilities in 1979 which revealed that 82% of the most labor intensive patients were in hospital outpatient units. In addition to these preferential admissions, HCFA data reveals a higher home training rate in hospitals. The hospital outpatient population is thus concentrated into a more complex, labor intensive group by these preferential admissions and by the transfer of the hospital's most stable patients into the home.

HCFA is proposing a de facto "single rate" system which penalizes hospital dialysis providers and is not consistent with Congressional intent. This de facto single rate system is based on a faulty methodology and uses data which is old, unsubstantiated and not consistent with current cost experiences. The audit data was hastily collected, arbitrarily adjusted and in many cases derived only from reporting forms rather than actual audits. HCFA acknowledges that it does not know whether as many patients of high cost facilities actually require as high a level of care as indicated by the costs, however, assumptions are made as though this possibility didn't exist. Consequently, HCFA proposes severe and abrupt reductions in hospital reimbursement by deriving reimbursement rates that fail to realistically account for hospital costs. HCFA's proposed methodology derives hospital allowances from the universe of providers rather than from hospitals alone. In determination of the labor and overhead differentials for hospitals, HCFA calculations result in inadequate reimbursement for hospitals and rewards independents with a $62 million windfall.

We believe that hospital labor costs can be reduced in many areas. However, we believe the labor cost allowance per dialysis in hospital facilities should be reimbursed at the median cost of hospital alone and that the overhead differential is a valid hospital cost and should be reimbursed as such.

We believe a dual rate reimbursement system which allows for realistic reimbursement of hospital dialysis treatments will avoid serious disruptions in service in a highly complex and vulnerable group of patients. We recommend this system be phased in over one to two years.

Our concern over reimbursement rate reductions is closely tied to our concern over the vague and imprecise exceptions process. The proposed regulations delineate categories under which a facility might qualify for an exception, but clearly defined criteria are absent. For example, the regulations require facilities to compare their atypical patient mix to other facilities with a similar atypical mix. Data for making such comparisons is non-existent and it is unlikely that another "similar" facility could be identified in this diverse system. Clearly an unreasonable burden.

We believe that significant regional differences exist in this highly diverse and complex treatment arena. We also believe that the complex and poorly described process of physician choice of modality and patient choice of modality, interrelating with medical complications, facility admission criteria and available treatment resources combine to create these differences. It is vital that all facilities have a clear understanding of this procedure in order to prevent unnecessary disruptions in service. We urge a careful definition of criteria utilizing an accepted common data base for decision making in this crucial area.

As previously noted, hospitals have home trained 75% of patients currently using this treatment location. We contend that the above mentioned penalties on hospital providers and the proposed changes in the home dialysis regulations will conspire to reduce, not enhance, the use of home dialysis. Inherent with Congressional intent is the belief that increased use of home dialysis will reduce Medicare ESRD costs. Furthermore, the composite rate is intended to stimulate home dialysis via the facility's ability to retain excess revenues. It appears likely that many hospital dialysis facilities in Northern California, and perhaps other states, may be forced into significant alterations in their delivery of services under the proposed reimbursement rates. Facility closure is one possible alteration. This will reduce the availability of home training services. Further, the elimination of the 100% equipment reimbursement provision will increase the cost to facilities providing home dialysis services. Hospital capital resources are scarce and declining. This disincentive, elimination of 100% equipment reimbursement for facilities, is coupled to a patient disincentive--an increase in co-insurance costs. The lower co-insurance costs associated with home dialysis have been the only home dialysis incentive for patients. We believe this 100% reimbursement option should be retained and the composite rate adjusted accordingly to allow for continuing equipment purchases by the HCFA. Other patient-oriented incentives should be explored as well.

The continued inadequate reimbursement for home training activities in another major disincentive. Facility financial losses in patient training require 6 to 12 months of home support activities for recovery. We suggest development of a flexible reimbursement method, such as a lump sum payment, that allow for interfacility differences and possibly serve as a facility incentive.

The retention of the direct billing option for patients will increase the cost of dialysis. This elective allows patients to bill directly for supplies and equipment and ignores the benefits of facility cost controls, volume purchases, etc. It also circumvents the composite rate incentive for the facility as facility payments will be limited to "support" activities. We propose that facilities, not patients, be given this option.

We urge careful reconsideration of the home dialysis regulations with an aim to developing bona fide incentives and elimination of major disincentives.

Finally, we are gravely concerned with patient well being. Proposed reimbursement cuts are taking priority over quality of care issues. HCFA's acknowledged poor data has not prevented proposals aimed at cost savings. These proposals will take place in a system virtually devoid of quality controls. Administrative support for quality assurance has not been clearly stated. Quality of care changes can only be assessed by adequate data developed over considerable time. We urge a system-wide assessment of quality which must be done concurrently with the rate reductions as the potential adverse consequences may not be detectable for several years.

In summary, we urge a realistic dual rate system which promotes efficencies without compromising access to care nor the quality of that care. Thank you.

Chairman RANGEL. Doctor.

STATEMENT OF ANN THOMPSON, M.D., DIRECTOR, DIVISION OF RENAL DISEASES, GEORGE WASHINGTON UNIVERSITY HOSPITAL, WASHINGTON, D.C., ON BEHALF OF AMERICAN HOSPITAL ASSOCIATION

Dr. THOMPSON. Good morning. Mr. Chairman, I am Dr. Ann Thompson, director of the division of renal diseases at George Washington University Hospital. I appreciate the opportunity to appear before the subcommittee on behalf of the American Hospital Association to testify on the proposed regulations establishing new prospective payment rates for outpatient dialysis services.

I have submitted a written statement which contains a detailed analysis of the proposed rates and I ask that my entire statement be submitted for the record.

Chairman RANGEL. Without objection, the entire panel's statements will appear in the record.

Dr. THOMPSON. Thank you.

My oral presentation and response to followup questions are based on 13 years of personal experience with the ESRD program at a major teaching facility, during which time I have been involved with the hospital-based dialysis center, the home training programs at the center, and the freestanding for-profit dialysis satellite facility. My experience with the program in each of these settings allows me to view the issue from all sides.

Questions concerning the technical aspects of the regulations and the data and methodology in my presentation should be directed to the American Hospital Association. I will confine myself to my own experiences.

One of the major controversies involved with the proposed regulations is whether there are legitimate differences between hospital-based and freestanding units that justify paying higher rates to the hospital units. I believe this controversy is caused by two major problems. One problem is that a methodology has not been developed for determining what the costs are at different centers that raise them above the current payment screen.

Another problem is, hospital units vary in terms of what they do. Some hospital units are no different from any other freestanding satellite dialysis unit. Other hospital units are, by reason of their traditional role in the community, geared to accept very difficult to manage patients.

For example, the dialysis program at George Washington University Hospital started as a home training unit. We progressed to an in-center unit combined with a home training unit then gradually changed to a center where normally the very difficult to dialyze and acutely ill patients were kept and all the other patients were transferred to a freestanding satellite. We are now going back to being a more mixed type program.

If you look at the patients we have dialyzed at George Washington University and those patients that many other dialysis centers within hospitals have been handling, you would find that they are the more seriously ill and hard to manage patients. It has been hard to document this in writing, but I would like to submit as a part of my testimony a set of patient acceptance guidelines from a freestanding patient dialysis facility affiliated with George Washington. I received them recently when the freestanding satellite center was refusing to accept back into the center a patient who had been transplanted at George Washington. The transplant ultimately failed and the patient was required to go back on central dialysis. However, the freestanding center did not want to accept the patient.

The reason was, the patient was very ill. There were a lot of problems which required a 1-to-1 patient-to-staff ratio. The freestanding facility referred her back to us and provided us a copy of their guidelines. I am in no way critical of the guidelines and in fact, feel they are reasonable for a satellite center.

They say that an outpatient chronic facility is by definition one that provides out of hospital ambulatory care for those patients whose health enables them to reside and be mobile within the community. They must have the ability to get to and from the facility. Patients who are so severely unstable during dialysis that they require constant 1-to-1 patient-staff ratio may not be accepted in this facility.

Patients must be at least partially weight bearing and require minimal assistance to get in and out of the dialysis chair in preparation for treatment. Patients must possess a reasonable level of mental competence and be oriented to place, time, and person. The patient must not represent a threat to himself or others within the facility.

Examples include patients who are physically destructive and may pull out lines and needles, patients who are verbally abusive and utilize foul language and with whom communication is impossible, patients who refuse medical treatment during dialysis and endanger their health.

One month after admission and quarterly thereafter, the patient's health profile will be reevaluated by the health care team to insure the patient continues to meet these guidelines. If the guidelines are not met, the patient will be discharged.

The patients who are abusive, are not mentally competent, who are wheelchair bound and cannot get themselves from a wheelchair to a chair for dialysis, patients who are so unstable because of cardiovascular problems that they require 1-to-1 nursing to patient ratio, are the patients that we dialyze in the hospital units such as George Washington University. Patients who are very stable, who require minimal care and who do not in fact do their own dialysis are sent out to satellite centers closer to their homes, which enables them to participate more fully in their home life and in the life of the community. I think this is true of a large number of economic centers.

I think if you would look at the hospital dialysis centers that exceed the screen, you might get a better idea why some centers have higher costs than if you continue to lump together all hospital dialysis units as though they were exactly the same kind of unit regardless of what hospital or where it was located.

Chairman **Rangel**. You said exceeded the screen. What does that mean?

Dr. **Thompson**. There has been a screen in the past set for the facility rate. The current screen is $138 per dialysis for a facility. That is considered the screen. Freestanding and hospital-based centers are not allowed to exceed that screen unless they have applied and been granted an exemption by HCFA. According to HCFA, current costs per treatment at approximately 46 percent of the hospital-based centers exceed the rates proposed on February 12.

I think if we looked at the group of hospitals that exceed the current screen we might be better able to determine how much of these increased costs are due to inefficiencies in operation and how much is due to a different mix of patients in those particular units. This is something that has not been done in the past, however.

In addition to that, many hospital centers have standing written affiliation agreements with freestanding satellite centers in which they promise to provide services, such as renal transplantation and backup dialysis for acutely ill patients. At GW, for example, we have such agreements with six freestanding satellite centers. The only connection they have with us is that we do their renal transplants and take care of their very sick patients. If the patient becomes ill and can no longer be safely treated in the satellite center, they are transferred into our hospital and we take care of them until they are stable or indefinitely, if they cannot be brought to a stable state.

Furthermore, we are obliged to provide 24-hour around the clock services for emergency care of these patients, which is something no freestanding unit has to provide. A freestanding unit doing 24-hour dialysis is probably doing it on a regularly scheduled basis, not just keeping extra staff available for emergency situations.

It has been somewhat difficult over the years to determine how much the cost per dialysis treatment is affected in each center by the caring of less stable patients. For a variety of reasons, over the past several months our center at GW has gradually been going back to containing more and more of the chronic patients in the center at the hospital rather than referring them to satellite facilities.

I have asked our financial services department to analyze the current costs of doing dialysis for this fiscal year compared to last fiscal year. I am talking about a relatively small number of patients. There are 23 patients dialyzing in the hospital center at present.

Our costs per dialysis this year compared to last year are estimated to be $20 less per dialysis because of keeping a small number of stable patients in the hospital center. We are still doing all the unstable patients. All we have done is add 15 stable patients to our unstable patients, and by doing that and using our services somewhat more efficiently we have already cut the cost by about $20 per dialysis.

There is no question if we could expand to a very large number of patients we could swallow the cost of the less stable patients even better. Of course, we cannot do that inside a hospital unit.

Chairman **Rangel**. Are you saying, doctor, that you are getting stable patients in in order to support the excessive costs of the unstable patients?

Dr. THOMPSON. No; we did not do it just to support the costs of the unstable patients. There were a number of reasons why we decided to keep most of the end-stage renal disease patients treated at the university hospital within our system, rather than referring all of the stable patients out as we had in the past.

In doing this, we have also been able to put half of the patients who are stable in the system on home dialysis. This is one of our goals. We wanted to have a home dialysis screening program again. We have 21 programs doing CAPD, which is much more pallatable to most patients than home hemodialysis seems to be.

But in the process of doing that, I wanted to see if it made any difference in our per dialysis cost, and it does make a significant difference. So far the direct costs are at least $20 less per dialysis. I use this only to prove the point that there really is a difference in taking care of primarily unstable patients versus primarily stable patients.

Other things which increase the cost burden on dialysis centers include the traditional emphasis in the hospital-based centers on doing home dialysis. Currently hospital units have about 23½ percent of their patients on home hemodialysis versus about 10½ percent at free-standing centers.

Under the current reimbursement system, there is no facility fee for taking care of home hemodialysis patients. However, if you have patients at home doing dialysis you have to have support services to help those patients. They require among other things more social services than in-center patients. They require help from the nursing staff. They require help from the dietary department.

The cost of maintaining those patients at home increases what ultimately becomes the per dialysis cost for the in-center patients, because those costs are charged to the dialysis unit, yet there is no separate fee the facility can charge for taking care of those home patients. I think it is ironic that hospital units which have been most supportive of home dialysis in the past are being doubly penalized for the support.

In the past we were not getting paid separately for those patients. Part of our increased costs reflect taking care of them. And now hospital-based units are criticized for being too expensive and being considered as inefficient operations.

In addition, the method HCFA used to compute the composite rates directly penalizes the hospital-based facilities because we have more home dialysis patients. We are being punished for successfully encouraging in the past the very type of dialysis you now want to encourage through the use of the composite rates. Unfortunately, the proposed rates may have the reverse effect by actually discouraging facilities from doing more home dialysis in the future.

Mr. MARTIN. Mr. Chairman, may I follow that point just for a moment, and then I will wait my turn? I would like to ask it and I may fail to figure out what my note means when I come back to it.

You describe the facility cost being charged to an outpatient or an inpatient, I am not sure which, rather than to the patient for whom it is realized, that is the home dialysis patients. Now, my question is, would it be a workable thing to allow facility cost for the home dialysis patient to be separately billed?

Dr. **Thompson**. Yes. That is workable.

Mr. **Martin**. And that would solve the problem you described, would it not?

Dr. **Thompson**. That is one of the things that now are part of the new proposed regulations, that the facility would be able to charge a fee for the home patient as well as for the center patient.

Mr. **Martin**. I see. That is in the proposal?

Dr. **Thompson**. That is part of the proposed regulation. But it has not been true in the past. Part of the increased costs are costs for taking care of these patients.

Mr. **Martin**. But to the extent that that works, it should serve to reduce that differential?

Dr. **Thompson**. If it is based on real figures. But what is happening——

Mr. **Martin**. To the extent it is charged at all, it will reduce the differential between hospitals with high percentage of home dialysis patients——

Dr. **Thompson**. One of the things you must realize is, the new rates proposed are composite rates based upon previous experience doing home dialysis. As I stated earlier, hospital-based facilities have 23.5 percent of their patients on home dialysis while the percentage for free standing units is 10.5. Therefore the percentage figure that is used to compute the composite rate is lower for the hospital units than it is for the free-standing centers, because we have more patients on home dialysis.

In addition HCFA, in computing the proposed rates does not take into consideration the reasons why 46 percent of the hospitals have higher rates. Are the hospitals within the 46 percent those that provide care for most of the home dialysis patients? Nobody knows.

The assumption is being made that home dialysis is a cheaper method. That is true overall. In the long run it is a cost saving process. But we are not looking at which units under the previous system were supporting home dialysis and which costs should we use as a baseline for establishing the new fees right now. We are totally ignoring this in our calculations.

Mr. **Martin**. Thank you.

Dr. **Thompson**. Hospital units frequently must pay higher costs for supplies than the large chains of free-standing units. I understand fully that HCFA is not particularly interested in feeling sorry for smaller, less efficient operations, and that their interest is primarily to provide service to the end-stage renal disease population in the most efficient manner possible. However, I think it is essential to look again at overall costs, not just the costs for in-center dialysis.

It is true that costs for dialysis in a lot of hospitals is more expensive than it is in free-standing centers. But on the other hand, the hospital centers have traditionally been those centers which supported renal transplantation, home dialysis, CAPD. These are the centers which have come up with most of the newer methodologies in providing more efficient and cheaper treatments.

I am not sure that it is the best overall strategy in terms of cost savings to drive out smaller, perhaps less efficient operations and leave only large chains of free-standing centers which are efficient, unquestionably, at providing a single service and could continue to provide that single service in a relatively cheap and efficient manner, but which may not devote money to research so new, better and cheaper forms of treatment may be developed. This may cost more initially but ultimately it will lead to much larger savings in terms of the care of these patients.

I also think that we should not ignore the educational role that many of the hospital centers provide. In a teaching hospital the dialysis unit costs, like all other costs in the hospital, will be influenced somewhat by their educational role. I can tell you from my center at George Washington, currently $12 per treatment is money used to provide educational programs. So I could save $12 per treatment right away by not doing education.

But if we do not, there will be no physicians capable to care for these people in the future, nor will we have people capable of doing research to find cheaper and better treatment methods or to find ways to prevent renal failure so that we will not have to have an ESRD program at all.

Thank you.

[The prepared statement follows:]

STATEMENT OF THE AMERICAN HOSPITAL ASSOCIATION PRESENTED BY ANN THOMPSON, M.D., DIRECTOR, DIVISION OF RENAL DISEASES, GEORGE WASHINGTON UNIVERSITY HOSPITAL, WASHINGTON, D.C.

Mr. Chairman, I am Dr. Ann Thompson, Director of the Division of Renal Diseases at George Washington University Hospital (GWUH) in Washington, D.C. I am testifying on behalf of the American Hospital Association which represents 6,300 institutional members and 35,000 personal members. I appreciate this opportunity to comment on the operation of the Medicare End Stage Renal Disease (ESRD) program and the Health Care Financing Administration's (HCFA) proposed regulation establishing a new prospective payment rate for outpatient dialysis services.

The ESRD program has attracted considerable attention, largely because of its growth and impact on Medicare costs. Approximately 654 hospitals provide outpatient renal dialysis services. HCFA data indicate that when the program started in 1974, 11,000 patients received ESRD services under Medicare at a cost of approximately $229 million, a yearly cost of $20,800 per patient. In 1981, 68,200 ESRD patients cost Medicare approximately $1.5 billion, a yearly cost of $22,000 per patient. Thus, while the number of patients increased more than sixfold in seven years, the cost per patient treated has increased only 5.8 percent.

Despite the reason for program growth—patient demand—HCFA's proposed regulation of February 12, 1982 seeks reductions in total ESRD outlays rather than addresses the problem's cause—the drastic increase in the number of patients receiving benefits. We find this rationale faulty since it ignores the primary reason for escalating program costs. We doubt the regulations will achieve the mandated objective of significantly reducing program costs through incentives for home (self) dialysis.

Rising program costs motivated Congress in 1978 to require the formulation of a reimbursement structure which would encourage cost efficient delivery of dialysis services while ensuring quality care and accessibility of services. Last year, as a follow-up, Congress enacted legislation (Section 2145, P.L. 97-35) directing the HHS Secretary to develop a composite rate structure which would encourage all facilities to increase utilization of less costly home dialysis services. In addition, Congress required that "separate composite weighted formulae" be calculated for hospital-based and for other renal dialysis facilities. This Congressionally mandated, dual rate structure came soon after HCFA had proposed a single prospective rate based only on the median costs of nonhospital facilities. AHA applauds Congress for its insistence on a dual rate structure which recognizes legitimate differences between costs in hospital-based facilities and costs in facilities not related to hospitals.

AHA believes that the prospective payment rates should encourage selection of the least costly appropriate form of treatment for each patient. These rates, however, also must be adequate to ensure that all levels of treatment will be available. There may be some patients currently being treated in hospital-based outpatient facilities who can safely be moved to less costly settings.

The House Ways and Means Committee report accompanying Section 2145 noted "that since enactment of the (renal) Amendments of 1978, there has been a modest increase in the number of end stage renal disease (ESRD) patients self-dialyzing at home." Further, the Committee notes that "a substantially greater number of renal patients could be dialyzed in the home setting * * *." Also, "the Committee recognized that not all patients are medically appropriate candidates for home dialysis * * *." Home dialysis requires a great deal of patient education and compliance as well as a stable, reassuring home environment.

The group of patients, unfortunately not yet clearly categorized, who are considered to be difficult to manage either because of medical instability or psychologic impairment, who must be treated in the hospital-based setting and will have to be treated there in the future. Those patients require a higher level of staffing and according to some, including the HCFA, believe this process results in "inefficient" operations. There has been a great deal of controversy as to the truth of this statement and the extent to which providing care for such unstable patients may influence the costs incurred in providing dialysis services. Attached to this statement are copies of patient selection policies currently in effect at two different groups of free-standing dialysis centers. One of these was recently sent to my colleague, Dr. Kramer, attached to a memo specifically refusing to accept back into the free-standing center a patient whose renal transplant had failed. This patient, for a variety of reasons, required a one-to-one staff to patient ratio and was perceived as being "disruptive" of the routine in the free-standing center. This is precisely the type of patient for which many hospital centers provide care. Additionally, many hospital centers have written affiliation agreements with multiple free-standing centers which clearly specify that the hospital center will act as "back up" for the free-standing center and provide care for patients who are difficult to manage and require a more intensive level of care than the free-standing facility can provide. GWUH, for example, has such agreements currently in effect with six free-standing centers.

Accessibility is the key element of the ESRD program—dialysis services must be available to all who suffer from end stage kidney disease or they will die. Improper rates could impede delivery of the most appropriate level of care.

HCFA POLICY BIAS

In an internal memorandum, HCFA acknowledges that the rates are on average set below current payment rates, "and that the agency's prime motivation in selecting its methodology was to get as close to a single rate as possible. HCFA states in the memo that one of the major advantage of its methodology is the provision of "flexibility to revise the adjustment for hospital-base facilities in later years and perhaps phase it out altogether." The document also states that the methodology "minimizes the differential between hospital-based and independent rates." Such statements reveal that HCFA is predisposed toward a single rate structure and in fact has developed a structure that can be adjusted easily to meet that goal.

HCFA PROPOSAL

Having expressed our concerns with HCFA's failure to address the overriding problem of ESRD program growth and our feeling that the proposal regulations are not fully responsive to the intent of Congress when it passed Selection 2145 of the Omnibus Reconciliation Act of 1981, we now identify specific concerns relating to HCFA's development of new prospective payment rates. Those concerns have to do with the inadequacies of the data used to arrive at the prospective rates, the rate-setting methodology itself, and the exceptions process outlined in the proposal.

HCFA's proposal does, however, correctly identify a problem with the current law that discourages the statutory objective of increased home dialysis. This is a valid point. The law permits home dialysis patients to bill the program directly for supplies and equipment rather than bill through the facility. Currently, many home dialysis patients use the direct billing option. Since there is nothing to discourage the continuation of this practice, the theoretical incentive which the composite rate gives facilities to move patients from in-facility dialysis to home dialysis is virtually eliminated.

In the past few months at GWUH, we have managed to train approximately half of our patients to perform Continuous Ambulatory Peritoneal Dialysis (CAPD) so that our home dialysis program has almost as many patients as our in-center program. Under the current reimbursement system, there is no facility fee for maintenance of home dialysis patients. Yet these patients require the services of employees of the facility such as nurses, dieticians, and social workers. In fact, particularly in the case of the social workers, the home patients may require more, rather than less, assistance than the center patients. Therefore, the home patients add considerably to both the direct and indirect costs for the facility which supports them. It is somewhat ironic that at a time when the ESRD program is emphasizing the importance of increasing the numbers of patients performing home dialysis, the very centers which have been most active in encouraging this form of treatment should be doubly "punished" for their efforts in this area. When the costs of some of the services are included in the overall per dialysis costs of the center, they are seen as reflecting only costs per treatment for the in-center patients and the hospital unit is then criticized for its "inefficient" operation. The calculations currently proposed for arriving at a composite rate are addressed more fully later in our statement. It is important for the Committee to understand that one impact of the formula used is to lower the rate for hospitals and thus, penalize them because they currently treat more patients in the home.

DATA BASE

The data used to develop the rules and composite rates for outpatients dialysis are incomplete, and by HCFA's own admission, subject to criticism. The Inspector General and General Accounting Office have also raised concerns about the adequacy and completeness of the data, and questioned the usefulness of the data as a basis for developing reasonable and reliable rates.

The House Ways and Means Committee report accompanying Section 2145 assumed that "adequate cost data should be available on which to establish costs for the home dialysis component of the composite rate" because the Medicare program has been paying for this service since 1973. To the contrary, evidence shows the data base is extremely weak and deficient. Also, AHA is very concerned that no patient mix data are available to reflect differences in intensity and resources of different types of dialysis providers. Without this type of data, rate setting is simply arbitrary.

Moreover, there are apparent disagreements among HCFA staff over what the available data actually show. Representative L. H. Fountain, chairman of the Government Operations Subcommittee on Intergovernmental Relations and Human Resources, during a recent hearing on the administration and management of the ESRD program, entered into the record a February 22 document prepared by staff of HCFA's Office of Research, Demonstration and Statistics which states that, "there may be differences in patient mix between freestanding and hospital-based facilities which could impact on the costs of providing services to the ESRD population." The HCFA staff, while acknowledging a lack of conclusive evidence, notes "the fact that hospitalization rates are higher for hospital-based facility patients could be related to greater need levels. . . " HCFA thus made policy decisions without collecting relevant patient data.

COST DATA

Although the statute mandates dual rates, HCFA is using a median cost value for all providers and is simply making several arbitrary adjustments in developing different rates applicable to hospital-based and other renal providers. This approach provides only a minimal adjustment for hospitalbased services.

In fact, the internal HCFA memorandum we refer to earlier clearly identifies the approaches taken by HCFA to arrive at its proposed rates. The memorandum notes the intent of Congress to have HCFA develop a dual rate structure but also notes that compliance with truly dual rates "reduces potential program savings."

We believe it is extremely important for this committee to review the rationale used by HCFA in developing proposed dialysis rates. HCFA acknowledges in the memorandum that "the cost of furnishing dialysis varies widely. Some facilities reuse dialyzers, make greater use of paramedical or nonprofessional personnel, or have lower staff-to-patient ratios. We (HCFA) do not know at this point what the optimum combinations are and how the cost of dialysis correlates to these variables. For example, we (HCFA) do not know whether as many patients of high cost facilities actually require as high a level of care as indicated by the costs. Nor do we (HCFA) know the extent to which patients participate actively in their own care in order to reduce labor costs."

Thus, the proposed cost bases do not reflect the legitimate cost differences among renal dialysis providers. Rather, "in the absence of a definitive standard for an efficiently and economically operated facility", HCFA is relying solely on a median cost determination. Yet, HCFA had acknowledged cost differences between hospital-based facilities and other renal provides for labor, overhead, and supplies. However, no attempt has been made by HCFA to fully explain why these differences exist or to develop the data which will either substantiate or refute hospial-based dialysis costs levels.

For example, HCFA contends that all dialysis providers should incur the same costs for supplies and, therefore, discounts as irrelevant the fact that hospital-based facilities' supply costs are $4 higher on a per treatment basis than the supply costs of other facilities. Nevertheless, HCFA acknowledges hospital-based programs are on average considerably smaller than independent facilities, and that the wide dispersion of hospital-based units results in higher transportation costs. Economies of scale have not been adequately evaluated.

Other factors also bear directly on costs. For example, under Medicare and state laws, hospitals must meet stringent life safety and staffing codes, therefore incurring higher operating costs than do freestanding facilities. In the ESRD netword many hospitals serve as back-up to independent facilities for more serious cases. These responsibilities lead to hospital labor costs that are $20 per treatment higher than labor costs in independent facilities. HCFA did not collect data on these factors and has chosen not to make any adjustments for them.

I understand fully the attitude that HCFA is most interested in providing services to the ESRD population in the most efficient manner possible and not in feeling sympathy for the higher costs incurred by smaller, "less efficient," operations. However, I think that it is essential that we look at overall costs, not just at the cost for in-center dialysis. While it is true that the cost per in-center dialysis treatment is frequently higher in a hospital vs. a free-standing unit, we must remember that the major stimulus for other, ultimately cheaper forms of treatment has come from these same units. We have already mentioned elsewhere the higher percentage of home dialysis supported by the hospital units. We must also remember that the major stimulus for renal transplantation is also coming from these units. At GWUH, for example, the Division of Renal Diseases employs a nurse whose major function is to provide patient and staff education about renal transplantation, not just to our own dialysis center, but also to the affiliated free-standing centers. This is a positive force increasing the number of patients who opt for renal transplant. Traditionally, the innovations which lead to new, hopefully better, and often more efficient care for ESRD patients have come from the hospital uints—not from units which operate primarily as very efficient providers of a single, standardized type of treatment to all of their patients. In the long run, driving hospital units out of business by a forced "competition" with free-standing centers dealing primarily with stable patients receiving a standardized treatment may prove to increase rather than decrease the costs of the ESRD program.

Until recently, our unit, like many hospital units, have referred stable dialysis patients to free-standing "satellite" centers and maintained in the hospital unit only those patients who are perceived as being too difficult to manage in the free-standing center. Over the past few months, we have begun to retain stable as well as unstable patients in the hospital unit. At my request, our Financial Services Department recently provided me with the current estimated costs of a dialysis treatment in our unit. Despite the fact that we are still looking at a relatively small chronic in-center population (23 patients) the direct costs per dialysis (i.e., the costs for labor and supplies are estimated to be $20 less than last year. I believe that this figure exemplifies quite well the significant cost burden incurred by many hospital units in dealing with a predominantly "sicker" dialysis population, particularly when one remembers that this small number of patients continues to include some patients unacceptable to the free-standing centers because of medical or psychological problems.

Therefore, we believe it is highly inappropriate to make critical assumptions in developing a reasonable cost base without thoroughly researching why these cost differences exist.

COMPOSITE RATE FORMULAS

HCFA's proposed incentive payment rule presupposes that the number of renal patients potentially able to dialyze at home "could approach 30 to 40 percent within five to seven years." If this is a valid target, then hospital-based facilities already have achieved considerable progess in meeting it because HCFA data reveal 23.5 percent, or almost one out of four hospital-based patients, are on self-dialysis. Therefore, the weighting factor used by HCFA in its hospital-based composite rate formula may be overstated and may by a disincentive for hospitals to transfer additional patients into the home dialysis mode.

HCFA acknowledges in the decision memorandum that an inconsistency exists. We urge that Congress evaluate the appropriateness of the HCFA weighting factor.

It should be apparent that future increases in proportional home dialysis services are unlikely because the proposed formulation penalizes the shift towards more cost-efficient delivery.

EXCEPTIONS PROCESS

In lieu of having accurate cost and other data, HCFA has included, as required by Congress, an exceptions process. This process is intended to provide relief from the proposed rates if valid reasons exist.

Since so little aggregate data are available on the program, generally an individual hospital will find it difficult to demonstrate its justification for an exception. In fact, HCFA states that it expects to grant few exceptions. We find this unacceptable and contrary to Congressional intent which calls for a process to recognize "the added costs of facilities, usually hospitals, whose dialysis services are largely geared to less stabilized, more costly patients. * * *"

RATE ADJUSTMENT

HCFA plans to use a 5 percent adjustment factor for hospital-based facilities because "any deficiencies in the (HCFA) data would impact the hospital-based facilities more than independent facilities. In addition, the use of the composite rate has a greater immediate effect on the hospital-based facilities, because the percentage of home dialysis patients is greater for hospitals than for independents."

HCFA Administrator Dr. Carolyne Davis told the House Government Operations Committee's Intergovernmental Subcommittee that the 5 percent factor was chosen instead of 10 or 20 percent in the interest of cost savings. According to Dr. Davis' testimony, the 5 percent adjustment figure is intended to account for: The possibility that the methodology used may have failed to recognize fully the legitimate cost of hospital-based facilities; any shortcomings in the audited data; age of the data; and the hospital-based labor component used in computation which adversely affects hospitals because the percentage of home dialysis patients is greater for hospitals than for freestanding facilities.

Thus, HCFA acknowledges that its rate methodology may be defective and does not properly recognize costs incurred by hospitals. It is clear from Dr. Davis' statement before the Intergovernmental Subcommittee that the 5 percent adjustment is purely arbitrary and that HCFA had no rational basis for determining the level. Rather, HCFA's motivation was solely to reduce costs and the adjustment is a token to partially offset shortfalls.

Even so, the proposed rule states that the rates will result in reimbursing 46 percent of all hospital-based and 28 percent of all independent facilities at a rate per treatment below their current costs for in-facility dialysis. This will confront hospitals with a difficult choice: whether to continue providing outpatient dialysis in the face of payment shortfalls or to discontinue this vital service.

SUMMARY

AHA is concerned with the growing cost of the end stage renal disease program and its impact on the Medicare costs. However, we believe most of the growing costs are not caused by inefficient and high-cost providers. Rather, we believe the major factor behind the program's growth is the steadily increasing number of patients. The per treatment cost is not a significant factor in program growth. AHA supports development of an appropriate policy to promote home dialysis.

AHA believes HCFA's proposed prospective payment rates are based on incomplete and suspect data. HCFA itself has admitted serious problems in that regard. As a result, the rates are inaccurate and do not even approximate the cost of providing outpatient renal services.

AHA wishes to emphasize that hospitals already have 23.5 percent of their patients on home dialysis. That represents two-thirds of HCFA's goal of achieving a 30 to 40 percent nationwide figure in the next five to seven years. We are concerned that the weighted composite rate may provide a negative rather than positive incentive to continue this trend.

We believe the proposed exceptions process is impractical. Only minimal relief can be expected because the burden of proof lies on the provider, and there are no data presently available to assist providers in presenting their arguments.

AHA finds unacceptable the fact that the proposed rates will adversely affect 46 percent of all hospital-based programs.

AHA RECOMMENDATION

AHA recommends that Congress require HHS to suspend its proposed rulemaking of February 12. We believe Congress should require HHS to perform a study within the next six months to yield the data necessary, including a patient-mix analysis, to develop a dual rate system that accurately reflects the costs of providing this lifesaving service. AHA would like to work with HCFA to design such a study.

We believe HCFA should not be permitted to implement prospective rates until such time as this study is completed. This restriction would result in a positive incentive for HCFA to perform the study quickly.

MID ATLANTIC NEPHROLOGY CENTER,
Suitland, Md., April 9, 1982.

DEAR DR. KRAMER: In reference to our conversation this morning. I thought you might like to see guidelines we developed several weeks ago. I am sorry we could not take ——— once again for dialysis.

Sincerely.

PATIENT ACCEPTANCE GUIDELINES

Mid Atlantic Nephrology Centers are out-patient dialysis facilities that offer safe and efficient dialysis for ESRD patients in our community. An out-patient chronic facility by definition is one that provides out-of-hospital ambulatory care for those patients whose health profile enables them to reside and be mobile within the community.

The following guidelines have been developed for patient acceptance to clarify the health care delivery in our dialysis facility and the limitations of its structure and ambulatory care.

(1) Patients must have the ability to get to and from the facility.

(2) Patients who are so severely unstable during dialysis treatment that they require a constant 1 to 1, patient staff ratio, may not be accepted in this facility.

(3) Patients must be at least partically weight bearing and require minimal assistance to get in and out of the dialysis chair in preparation for treatment.

(4) Patients must possess a reasonable level of mental competence and be oriented to place, time and person.

(5) The patient must not represent a threat to himself or others within the facility. Examples include: (a) Patient who is physically destructive and may pull out line or needles; (b) A patient who is verbally abusive and utilizes foul language and with whom communication is impossible; and (c) Any patient who refuses medical treatment during dialysis and endangers his health.

(6) A patient who has physically assaulted another patient or staff member, will not be accepted. Further, once admitted to the facility, a patient who physically assaults another patient or staff member will be discharged.

One month after admission, and quarterly thereafter, the patient's health profile will be re-evaluated by the health care team to insure that the patient continues to meet the acceptance guidelines. If these guidelines are not met, the patient will be discharged.

Chairman **RANGEL**. Dr. Gruskin, St. Christophers.

STATEMENT OF ALAN GRUSKIN, M.D., CHIEF OF NEPHROLOGY, ST. CHRISTOPHERS HOSPITAL FOR CHILDREN, ON BEHALF OF THE NATIONAL ASSOCIATION OF CHILDREN'S HOSPITALS AND RELATED INSTITUTIONS, INC.

Dr. **GRUSKIN**. I am Dr. Alan Gruskin, chief of nephrology at St. Christophers Hospital for Children in Philadelphia, and chairman for the National Association of Childrens Hospitals and Related Institutions' Council on End-Stage Renal Disease. It is in the latter role that I appear before the committee today.

I would like to summarize the written testimony we have submitted. We appreciate the opportunity to present our views concerning the proposed changes to the end-stage renal disease program.

We are supportive of a prospective rate reimbursement system for the end-stage renal disease program, provided it is based upon agreed-upon standards of care and operation and does not arbitrarily penalize any one group of patients or the providers of their care. The system as presented by HCFA in the proposed rule, however, poses a serious threat to the viability of Childrens Hospitals end-stage renal disease programs and their ability to continue to serve the child with renal insufficiency.

Today's presentation will consist of two parts. First we will address the child per se with end-stage renal disease. In the second we will consider the impact of the proposed changes on Childrens Hospitals caring for children with end-stage renal disease.

In 1980 children and youth under 20 years of age represented approximately 5 percent of the end-stage renal disease in the population. Historically, the programs have developed along lines in keeping with the mandate of the ESRD program, namely a high rate of transplantation and a high usage of home dialysis. Also, many pediatric programs, despite the small total number of patients, provide a wide breadth of dialysis and transplant services.

Data which have been collected from the Childrens Hospitals programs document that an aggressive treatment regime aimed at restoring normal renal function through early transplant is important. A recent survey of 117 children being dialyzed in Childrens Hospital programs found that 47 percent of these children had already undergone one or more transplants. Of the remaining children, 61 percent were currently awaiting a transplant. This figure may be contrasted to the average adult program, which report a transplant rate of approximately 9 percent.

The Childrens Hospitals programs emphasize a normal life style for the child. Nearly 80 percent of the children regularly attend school. Moreover, over 35 percent of the children receiving treatment are on home dialysis, a number double the overall national rate for home dialysis.

The unique characteristics of a pediatric population require more individualized and intensive care. Staff to patient ratios of 3 to 1 or 2 to 1 and better are common in pediatric programs.

The limited blood volume of children greatly reduces the margin of allowable variance before serious complications occur. The bulk preparation of dialysis is inappropriate for children, as individual dialysis prescriptions are required. Furthermore, properly trained staff must not only attend to the organic needs of the child, but also must be available for explanation and psychosocial support for the family.

The disease characteristics found in the child differ from those found in adults. The three most common diagnoses found in our pediatric survey were chronic nephritis, congenital uropathy, and renal dysplasia, the latter two being birth defects.

Renal failure having its onset during the first few months of life presents a set of clinical challenges clearly different from those seen in older children and adults. Problems in the area of growth and development occurred in 70 percent of these children. Careful monitoring of medication is critical if maximum growth potential and blood pressure regulation is to be achieved.

Experience has shown that the child with end-stage renal disease requires an increased intensity of laboratory services to assure that the dialysis prescription is adequate and that maximum growth and nutrition is achieved.

The net result of these differences experienced by children is an increased demand on staff time, greater inventories of supplies, more availability of equipment, a wider breadth of professional expertise, and greater use of laboratory services.

Next I would like to consider the impact of the proposed regulations on childrens hospitals caring for the child with end-stage renal disease. The above-mentioned factors combine to result in higher per treatment cost in the children's hospital program than in either free standing facilities or general hospital units.

Since the average cost per treatment in fiscal year 1980 for the children's hospital dialysis programs was $276, it is apparent that the children's hospital end-stage renal disease program will need to rely on achieving exemptions from the proposed and prospective average reimbursement rates of $132 or less if they are to recover reasonable costs for their services.

The proposed regulations indicate that an atypical patient mix may qualify a facility for an exemption to the reimbursement, but the burden of proof rests with the provider to demonstrate that its higher costs generate from this or other factors beyond its control. Our council senses that HCFA's intent is to develop such a body of knowledge through the exception request review process, rather than through independent analysis or prospective decisionmaking.

We regard this approach as placing an unnecessary stress on beneficiaries and institutions who are already known to have high costs. If childrens hospitals ESRD programs are not granted exceptions to the proposed reimbursement rate quickly and expeditiously, and if exceptions do not recognize the full cost of end-stage renal disease services, childrens hospitals programs will be in jeopardy and may be forced to discontinue services.

The childrens hospitals have been disproportionately affected by funding reductions occurring in health and social services. Childrens hospitals experienced over 60,000 medicaid admissions and 622,000 medicaid days, representing 30 percent of their total inpatient days in 1980. The fiscal base of tertiary childrens hospitals, especially those located in large urban centers, is being severely impacted upon by cuts in State medicaid programs.

To alleviate this imminent threat to institutions specializing in the care of children with end-stage renal disease, as well as other atypical patient groups, it is our position that the criteria upon which exemption requests are judged for appropriateness must be codified and known prior to the implementation of the proposed rules. Without these identified standards, providers seeking exceptions to the reimbursement rate will be forced to engage in a guessing game of serious financial proportions.

To this end, the association has under consideration the development of a uniform system of costing, budgeting and exception request preparation for use by childrens hospitals end-stage renal disease programs. The association intends to invite HCFA's participation in the development of such a system.

In order to ensure that children continue to receive appropriate age-related care, it appears to us that the development of a set of specific guidelines and regulations defining how pediatric end-stage renal disease programs can function efficiently, compassionately and without undue ongoing financial distress would best meet the needs of our children.

Thank you.

[The prepared statement follows:]

STATEMENT OF THE NATIONAL ASSOCIATION OF CHILDREN'S HOSPITALS AND RELATED INSTITUTIONS, INC.

Summary

- Pediatric ESRD programs have a higher cost per treatment than adult programs. This is due to their aggressive treatment philosophy and the high staffing level necessary to provide the intensity of services required by the complex patient-mix. The children's ESRD programs must rely on the exception process to recover reasonable costs for the services they provide.

- NACHRI is supportive of the change to a prospective reimbursement rate system for the End-Stage Renal Disease Program. The rate, however, must be based on articulated standards of care and operation and must not discriminate against any one group of patients or the providers of their care.

- The identification of the median cost of all dialysis facilities as the standard of efficient operation discriminates against hospital providers. The effect of this decision on Children's Hospital ESRD programs and the children they serve is potentially devastating.

- The exception process as developed in the proposed rule is inadequate. No indication as to the criteria which will be used by HCFA to judge the appropriateness of a request has been given. No limit on the maximum time by which HCFA must respond to an exception request is established. No indication is given as to what documentation a facility must present to receive an exception from HCFA.

- During the generation of the information necessary for approval of an exception request, providers will be underpaid for services rendered. Even if HCFA finds the higher program costs justifiable, a facility will be reimbursed for them only from the time HCFA accepts the request. No retroactive settlement is indicated in the proposed rule.

- This lack of clearly defined procedures for the exception request process undoubtedly will compromise the ability of HCFA to grant timely and appropriate exceptions to the proposed reimbursement rate. Such financial uncertainty may result in the reduction or elimination of Children's Hospital ESRD programs and place undue stress on the children and parents served by these programs.

STATEMENT

The National Association of Children's Hospitals and Related Institutions, NACHRI, welcomes the opportunity to present to the Sub-Committee on Oversight of the Committee on Ways and Means views concerning the proposed changes to the End Stage Renal Disease Program. It is in the interest of children with end stage renal disease that the comments are submitted.

NACHRI is composed of 73 Children's Hospitals, both free-standing and university hospital affiliated. Included among these institutions are the vast majority of the major teaching Children's Hospitals. Member hospitals admit over 90 percent of the patients cared for in Children's Hospitals and provide in excess of 2.3 million days of inpatient care per year. Additionally, they experience nearly 4 million outpatient visits a year, and conduct extensive educational and research programs. Annual expenditures on behalf of their patients exceed $1.2 billion.

The Association is organized in the recognition of the importance of child health care, providing a forum of hospitals which specialize in the care of children. Its main purpose is to promote the quality of child health care through the dissemination of information and the promotion of research and education programs related to that care.

In the performance of its mission, NACHRI has willingly accepted the role of advocate for the child. When policies, regulations, or legislative proposals germane to providers of health care reflect a particular impact on the needs of children NACHRI addresses them, pointing out their effect on child health care. In exercising this advocacy role for children, the Children's Hospitals speak to the rationale for their very existence. The acknowledgement that the child is different; different in his metabolism, in his reaction to the disease process, in his emotional and social needs, and in the methods of care needed to maintain or restore his normal health status provides the impetus for institutions dedicated solely to the care of children. This recognition of the unique characteristics and needs of the child population, specifically pediatric end stage renal disease patients, coupled with the child population's limited ability to speak to its own needs motivates the development and submission of this statement.

The Association is supportive of a prospective rate setting system for the Medicare end-stage renal disease program. The proposal for establishing a prospective system as presented by HCFA, however, threatens the ability of Children's Hospital ESRD programs to continue to serve the children afflicted with this disease. Following is detailed documentation of the unique characteristics of the child ESRD patient and of the Children's Hospital programs developed to respond to their needs. The impact of the proposed rule on both the child ESRD patient and their providers is also analyzed.

INTENT OF PROPOSAL

NACHRI recognizes the proposal's intent to control the rising cost of the ESRD Program and to eliminate inefficiencies, which HCFA feels will result from establishing a prospective reimbursement rate and encouraging home dialysis. Although the costs of the ESRD Program necessitate its cost effectiveness, it is apparent that the escalating costs are more a function of increased patient load than of inefficiencies in operation. A comparison of data for 1974 and 1981, demonstrates that while the ESRD patients covered by Medicare increased by over 600%, the cost per treatment increased by only 5.8%. These figures hardly suggest overall inefficiencies in the operation of the ESRD programs.

GENERAL CHARACTERISTICS OF PEDIATRIC ESRD PATIENTS AND PROGRAMS

In 1980, children and youth under the age of twenty represented 5.17% of the total Medicare ESRD population, numbering approximately 2,900. Fortunately, the incidence of end-stage renal disease in the child population is low. When it does occur however, the clinical challenge is significant. The manifestations of the disease in the child coupled with the attributes of children in general, result in an array of treatment needs which often differ from those of the adult end-stage renal disease patient.

There are 46 identified hospital-based ESRD programs with specialized capabilities for treating the unique needs of children. Thirty of these programs are located in university based hospitals or hospitals with a major teaching affiliation, and as a consequence, the majority do not segregate incidences of children's treatment for statistical purposes, nor are they able to isolate the cost of children's care. It is in the Children's Hospitals' programs, therefore, that the special needs of children and the full impact of their care can be measured. At the end of 1981 there were 16 Children's Hospitals providing the primary source of renal care to over 13% of the pediatric ESRD population.[1] These hospitals also serve as regional referral, consultation, teaching and research centers for the care of all children with end-stage renal disease.

The Children's Hospital ESRD programs are not maintenance-oriented but rather employ an agressive cure-oriented method of treatment which results in higher program costs, on a short term, unit of service basis. Yet, the goal of these pediatric programs is to restore normal renal function through transplant so that the child may develop to a healthy, productive adult, and as a consequence long term costs to society and to the ESRD program are reduced. This philosophy however, renders the children's programs particularly susceptible to adverse impact from the prospective reimbursement system as it is proposed.

IMPACT OF INCENTIVES FOR HOME DIALYSIS

The proposed composite rate is intended to encourage greater use of home dialysis. In fact, it will reward programs which have not encouraged home dialysis and show an experience below the 23.5% home dialysis rate for hospitals. Whether this rate can actually provide an incentive for facilities to increase their use of home dialysis is questionable. The proposed rate in fact appears to penalize providers who have already encouraged the use of this alternative treatment site. Indeed, there is an incipient penalty for a previously attained higher usage of home dialysis built into the rate setting methodology. If future base rates are to be determined by the same methodology, any shift to home dialysis above levels generally attained would actually serve to reduce the base rate for subsequent reimbursement. It might be argued that the provision of home dialysis is less costly, in justification of this lower reimbursement rate. However, in spite of the composite rate's having been designed to provide a facility the same reimbursement level regardless of treatment site, actual payment for home dialysis remains uncertain. Since the option for direct billing by patients on home dialysis is retained in the proposed rule, a facility is not assured of receiving the same per treatment reimbursement for a patient shifted from in-center dialysis to home dialysis. The greater the number of patients on home dialysis, the greater is the portion of total reimbursement that becomes doubtful.

Of the patients being treated in 13 of the Children's Hospital programs at the end of 1981, over 35% were on home dialysis.[2] This is more than double the overall national rate for home dialysis and represents a 37% increase over the percentage of children in these programs on home dialysis at the end of 1980. Under the proposed rule, the Children's Hospital programs may be penalized for having developed their home dialysis programs to this extent and having actually achieved the percentage of home dialysis that was identified as desirable in the department's testimony before the Senate Health Subcommittee.

IMPACT OF SELECTING MEDIAN COST OF LIMITED SAMPLE AS STANDARD OF EFFICIENCY

The Association supports the proposal to establish a prospective rate setting system for the ESRD program. Important criteria for such a system however, are that the base reimbursement rate be developed pursuant to articulated standards of care and operation and that the rate not discriminate against the care needs of any one group of patients or the providers of their care.

Even though HCFA and its predecessor the Bureau of Health Insurance have had responsibility for the ESRD program and have been collecting data on it since the early 70's, no standards of efficient operation have yet been promulgated. In the absence of such standards, the designation of the median cost from the selected sample of freestanding facilities and hospitals as the standard for efficiency is therefore unsubstantiated. Further, the use of the combined median discriminates against hospital providers while benefiting the freestanding units, since the median cost for the hospitals in the sample was $135 while the median cost for the freestanding units was $108. The effect of selecting the combined median as the standard of efficient operation is not only discriminatory towards the Children's Hospital providers, but is indeed potentially devastating to their ability to continue to serve the children in their programs.

FACTORS IN THE HIGHER COST OF CHILDREN'S ESRD PROGRAMS

The pediatric ESRD programs generally have a higher cost per treatment than both the freestanding facilities and the general hospital units. A number of factors combine to cause these higher costs. Data which have been collected from the Children's Hospital programs document that unlike adult programs where maintenance of life is the primary treatment goal, children's programs employ an aggressive treatment regimen and emphasize early transplantation, so that the growth and development process is compromised as little as possible. A survey of 117 children receiving care in Children's Hospitals' programs during September 1981, indicated that the average time between initiation of dialysis services for these patients and transplantation was 6.76 months. Forty-seven percent of the 117 patients had undergone 1 or more transplants. Of the remaining children, 61.3% were currently awaiting a transplant. This high incidence of transplantation is confirmed by a similar study of 115 pediatric patients conducted by Network 11 in Texas.[3] It found that 95% of the patients under 16 had either received a transplant or were current candidates for one. This is in marked contrast to adult programs which have a reported transplant rate of 9%.

The NACHRI survey also found that during the course of treatment prior to transplant, Children's Hospital programs place emphasis on maintaining a normal life for the child to the extent possible. The activities of a "typical" child revolve around school and home. The study shows that a high level of school attendance has been maintained for these children. Of the 117 ESRD patients surveyed nearly 78% of the school age children attended school on at least a part time basis. Complete results of NACHRI's survey are provided in Appendix A.

Another contributor to the higher costs of the Children's Hospital programs is the demonstrated high rate of turnover in the treatment of children. During three six months reporting periods, 7/80 to 12/80, 1/81 to 6/81, and 7/81 to 12/81, the turnover ratio was .49, .57, and .49 respectively. This turnover rate of approximately 50% results in continuing evaluation, orientation, and education of newly diagnosed ESRD patients, and preparation of children and parents for transplantation.

Labor costs also add significantly to the overall cost of the Children's Hospital programs. The unique characteristics of the pediatric population often require more individualized and intensive therapy, resulting in patient to staff ratios of 3:1, and even 2:1, being not uncommon in pediatric programs.[4] The small body size of the child ESRD patient requires close monitoring during dialysis, for maintenance of the proper fluid balance and medication level is critical. The limited blood volume of a child greatly reduces the margin of allowable variance before serious complications occur. The size and weight of the child may change quite frequently, requiring additional laboratory studies to assure the proper dialysis treatment is carried out at each treatment session. Furthermore, staff must not only attend to the needs of the child, but also must be available for explanation and support to the parents during the course of treatment.

The disease characteristics found in the child very often require more intensive treatment and also increase the demand for staff. To illustrate this fact, a comparison with data cited by Lowrie and Hampers to support their view that freestandings and hospitals treat clinically similar patients is provided.[5] They summarize the five most common diagnoses for a sample of patients on dialysis in 1980. (Since the mean age of this sample was 53.5, it is assumed to have been a predominantly adult population.) Similarly, disease characteristics were collected in the NACHRI study of children's programs. Glomerulonephritis was the most common primary diagnosis indicated for nearly 30% of the children, as it was most common for the adult sample. It is with this measure however, that the similarities between the two age groups end. The next two most frequent diagnoses for children were congenital obstructive uropathy and renal dysplasia, presenting great clinical challenge. The adult sample exhibited hypertension and diabetes as the next most common diagnoses, not evident as a primary diagnosis among the children studied.

The NACHRI study also considered complicating conditions. A mean of 4.81 complicating conditions per child was demonstrated. One of the more frequently cited conditions, potential growth retardation, was indicated for nearly 71% of the sample, and over 53% of children in the study were reported to have a definite poor growth potential. Since adults perforce have achieved full growth, problems in growth and development are not common complicating condition in the adult population.

Finally, supplies also tend to increase the cost of the children's programs. While the proposed rule indicates that hospitals should be exercising the same economies with regards to supplies as many of the large freestanding facilities, this is simply not a feasible option for the Children's Hospital ESRD programs. First, as a consequence of both the low incidence of ESRD in children and the need for a catchment area of reasonable size, the children's programs have small patient volumes, which in turn mitigates against large scale purchasing of supplies.

Second, factors such as blood volume, small body size and complicating conditions that vary from child to child render the bulk preparation of dialysate inappropriate for children, such that these programs frequently must prepare individual dialysate prescriptions. Furthermore, their supply inventories must contain a variety of sizes of items such as dialyzers to accommodate the needs of the children. Their purchase of supplies therefore is specialized, and necessarily more costly.

DEMONSTRATED COSTS OF CHILDREN'S HOSPITAL PROGRAMS[6]

During FY 1980, 13 Children's Hospital ESRD programs provided on average, 890 hemodialysis treatment sessions which were covered by Medicare. A total of 7,500 additional outpatient hemodialysis treatments were provided by these programs during FY 1980. The average cost per session was $276, an 8% increase over their cost per hemodialysis treatment in FY 1979. The total cost of hemodialysis treatments provided to Medicare patients in FY 1980 was $3.2 million, a small percentage of the total ESRD program costs. Of this total Medicare cost however, slightly more than one-third was above the payment screen in effect. Projecting a payment rate of $132 per dialysis treatment would result in over 50% of the Medicare costs for the Children's Hospitals programs being over the limit. It is apparent that the children's ESRD programs will need to rely on achieving exceptions to the proposed rate if they are to recover the reasonable costs for their services.

EXCEPTION PROCESS

The proposed rule indicates that an atypical patient mix may qualify a facility for an exception to the reimbursement rate. The burden of proof rests with the provider, to demonstrate that its higher costs generate from this or other factors beyond its control, without benefit of elaboration of these factors. This Association senses that the intent is to develop such a body of knowledge through the exception request review process, rather than through independent analysis. Since during the generation of this knowledge, providers of care may be placed in financial jeopardy and their ability to serve patients compromised, we regard this approach as putting undue and unnecessary stress on beneficiaries and institutions.

The provider must seek an exception within 180 days of notification of its reimbursement rate. The proposed rule however does not designate a time by which HCFA must respond once an exception is filed. Given the demonstrated slowness with which similar exception requests have been considered in the past, the provider may supply a considerable volume of services without knowing if or when full payment for their cost will be made. Further, once an exception is granted a facility is reimbursed at the higher rate commencing with HCFA's approval of the request. No settlement retroactive to the request's filing is indicated in the proposal.

The higher costs of children's programs have been recognized in the past, and 8 of the 13 hospitals were approved for some exception to the then target rate of $138. We are encouraged by this past acknowledgement of justifiable higher cost and further heartened by the designation of pediatric units as examples of programs with an atypical patient mix in the text of the proposed rule. While the provider of children's ESRD services can certainly document the special needs of the child ESRD patient and the effects of these needs on the programs established to serve him, the provider may be frustrated unnecessarily by the requirement to translate these results into cost differentials as compared to the cost of a "typical" facility. With no details on a typical facility provided in the proposed rule, the resulting situation becomes an attempt to solve an equation with only one variable known.

EFFECTS OF PROPOSED RULE ON CHILDREN AND THEIR PROVIDER

If the Children's Hospital ESRD programs are not granted exceptions to the proposed reimbursement rate quickly and expeditiously, their ability to continue to care adequately for the children in their programs well may be compromised. Further, if exceptions do not recognize the full cost of the services, these children's programs will be in definite jeopardy and may be forced to eliminate the service.

The Children's Hospitals, and more importantly the children they serve, have been disproportionately affected by the funding reductions that are occurring in health and social services. Children's Hospitals which in 1980 experienced over 67,000 Medicaid admissions and 622,000 Medicaid days representing 30% of their total inpatient days,[7] are being severely impacted by cuts in state Medicaid programs. An ESRD program which has not recovered its cost in the past and which may require a greater future subsidy while benefiting a relatively small number of patients, is not in an enviable position in the hospital faced with reducing services and programs because of less than adequate reimbursement for great numbers of other patients.

The reduction or elimination of ESRD programs serving children would be of great significance to the pediatric patients and parents served by these programs. It would require an adjustment to a different dialysis program with a different philosophy of treatment, not geared to the needs of the child. Furthermore, if the children are treated according to a program philosophy of maintenance-oriented care as opposed to cure-oriented care through transplantation, they will continue to generate program costs for years to come.

CONCLUSIONS

NACHRI agrees that the rising costs of the ESRD programs necessitates its cost effectiveness, although we recognize that these rising costs are a function more of increased patient loads than of inefficiencies of operation. We are also supportive of the proposal for a change to a prospective reimbursement rate system. However, this system must be based on agreed upon standards of care and operation, and must not arbitrarily penalize any one group of patients or the providers of their care.

We are encouraged that pediatric units are cited examples of programs with atypical patient mix at several points in the proposed rule, and we are willing to provide documentation to substantiate this position. We do not espouse a separate pediatric rate for ESRD services, since costs differ even among the Children's Hospitals, in varying stages of development of their ESRD programs. It is our position that the exception process must recognize that newer programs often experience the higher costs associated with start up and initial low utilization, and that this and other criteria upon which exception requests are judged for appropriateness must be codified and known. Without these identified standards, providers seeking exceptions to the reimbursement rate will be engaged in a guessing game of serious financial proportions, and HCFA faces the difficult challenge of avoiding arbitrary decision making.

To this end, the Association has under consideration development of a uniform system of costing, budgeting, and exception request preparation for use by Children's ESRD programs. Areas of concentration include direct and indirect cost elements, basis of cost allocation, intensity of lab and other ancillary services per patient, intensity of services to

ESRD patients as compared to other pediatric patients, and further elaboration on staffing levels. The Association would invite HCFA's participation in the development of this system. It may serve to refine the exception process by developing a prototype for profiling an atypical patient mix and quantifying the effects that their care has on program costs.

Sincerely,

Alan B Gruskin, M.D.

Alan Gruskin, M.D.
Chairman, ESRD Council

REFERENCES

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2 Children's Hospitals' 1981 Facility Surveys (Form HCFA 2744).

3 Hogg RJ, Murphy J, Conley S. Lynch R. *A Regional Network Review of Health Care Delivery to Children and Adolescents with End-Stage Renal Disease*. ESRD Network 11 Medical Care Evaluation Study for 1980-1981, p. 3.

4 Ibid., p. 1.

5 Lowrie EG, Hampers CL. *The Success of Medicare's End-Stage Renal-Disease Program*. The Case for Profits and the Private Marketplace. N Engl J Med. 8/20/81 434-438. p. 436.

6 Children's Hospitals' Medicare Cost Reports (Form 2552), Supplemental Worksheet E-3.

7 Children's Hospitals 1980 AHA *Annual Survey of Hospitals*.

Appendix A

RESULTS OF THE
PEDIATRIC ESRD PATIENT PROFILE

To test the appropriateness of the development of a profile of children with end stage renal disease, six children's hospitals with ESRD programs were asked to complete a patient questionnaire for each patient currently receiving maintenance dialysis services. The patient questionnaire was developed with the guidance of Alan Gruskin, M.D., and Paul McEnery, M.D., members of NACHRI's ESRD Council. This process provided a sample of 117 current pediatric ESRD patients.

PATIENT CHARACTERISTICS

Following are statistics displaying the demographic and socioeconomic characteristics of the patients in the sample.

- Sex

Male	58.97%
Female	41.03%

- Race

White	67.52%
Black	18.80%
Hispanic	11.11%
Other	2.56%

- Age

Mean = 13 years 8 months
Median = 14 years 1 month
Range = 1 year 6 months - 25 years 6 months

- Family Composition

% of Patients living with:		Avg. # of Siblings at home:
Both parents	62.39%	1.86
Mother	23.93%	1.67
Father	4.27%	1.60
Other	9.40%	1.90

- Family Income[1]

Less than $20,000/yr.	67.37%
More than $20,000/yr.	32.63%

- Patient School/Employment Status

Preschool age	7.69%
Attends school full-time	33.33%
Attends school part-time	35.04%
Tutor	3.42%
Unable to attend school	7.69%
Works part-time	4.27%
Unable to work	8.55%

- Patient School Performance (for 84 patients attending school)

Full-time above average	9.52%
Full-time average	28.57%
Full-time below average	8.33%
Part-time above average	1.19%
Part-time average	19.05%
Part-time below average	28.57%
Tutor average	2.38%
Tutor below average	2.38%

- Presence of Behavior Problems

Behavior problems present	40.52%
No behavior problems present	59.48%

DISEASE CHARACTERISTICS

Following are statistics illustrating disease characteristics of the patients in the sample.

• ESRD Primary Diagnosis		% of patients
Glomerulonephritis		29.91%
chronic undifferentiated	1.71	
MPGN	5.98	
FSGN	5.98	
RPGN	5.13	
Other	4.27	
Unspecified	6.84	

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[1] 49.1% of all families in the U.S. had an income level of $20,000 or more in 1979. U.S. Department of Commerce, Statistical Abstract of the United States, 1980. p. 450.

• ESRD Primary Diagnosis	% of patients
Obstructive uropathy, congenital	18.80
Renal dysplasia	11.11
Hypoplastic kidneys	5.98
Cystinosis	5.13
FGS	5.13
Other interstitial nephritis	4.27
Polycystic kidney disease	2.56
Wilms Tumor	2.56
Medullary cystic disease	2.56
Reflux nephropathy	1.71
Sickle cell anemia	1.71
Lupus	1.71
Other	6.84

• Presence of Complicating Conditions

Complicating Condition	% of patients
Renal osteodystrophy	83.76
Growth retardation	70.94
Neuropathy, peripheral	35.90
Seizure disorder	54.70
Psychomotor retardation	37.61
Cardiac manifestations	52.14
Cardiovascular	38.46
Hypertension	45.30
Nutrition	21.37
Anemia	5.13
Hypotension	2.56
Respiratory	1.71
Other	14.53
None	3.42

543 complicating conditions are currently present in 113 patients. The mean number of complicating conditions presented is 4.81.

• Ability to Walk

Good	52.14%
Fair	29.06%
Poor	17.95%
Unable	0.85%

• Growth Potential

Good	21.37%
Fair	25.64%
Poor	52.99%

TREATMENT CHARACTERISTICS

The following statistics demonstrate characteristics of treatment of children with end stage renal disease.

- Current Dialysis Treatment Modality & Setting[1]

  - Hospital Unit - 76.07% (89 patients)

Hemodialysis	76 patients (85.39%)
IPD	13 patients (14.61%)

  - Home - 23.93% (28 patients)

CAPD	19 patients (67.86%)
IPD	8 patients (28.57%)
Hemodialysis	1 patient (3.57%)

  - Duration of Current Dialysis Regime

Mean = 20.43 months
Range = 1 month - 96 months
47.41% of the patients have been on current dialysis regime for 12 months or less.

  - Months from Recognition of Progressive Renal Failure to Initiation of ESRD Services

Mean -	43.83 months
Median -	16.50 months
Range -	0 months - 271 months

Medications Prescribed

  - Total Medications Prescribed

Mean -	6.18
Median -	6.00
Range -	2.00 - 12.00

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[1] At the end of 1979, home dialysis patients represented 13.04% of the total dialysis population of which 94.3% were 19 years of age or greater. Programs End-Stage Renal Disease Second Annual Report to Congress, FY 1980, p. 1.

- Antihypertensive Medications Prescribed

Prescribed to 45.30% of patients

Mean - 1.72
Median - 2.00
Range - 1.00 - 4.00

- Transplant Experience (55 patients)

47.01% of the patients in the sample have received 1 or more transplants. The average number of transplants per patient transplanted is 1.51. 85.54% of the transplanted kidneys were cadaveric, and 14.46% were from living related donors.

- Survival of the Graft

Cadaveric (mean)	10.63 months
LRD (mean)	9.58 months
Total (mean)	10.52 months

- Average Time between Initiation of ESRD Service and First Transplant

Mean = 6.76 months

81.82% of the patients who have received transplants received their first transplant within 12 months of initiation of ESRD services.

- Patients Never Transplanted (62 patients)

52.99% of the patients in the sample have never received a transplant. 61.29% of these patients are currently awaiting transplant. 38.71% are not currently candidates for transplant.

- Average Time between Initiation of ESRD Service and Entry on Transplant Registry or Commencement of Preparations for LRD Transplant

For those patients who have never received a transplant and who are currently awaiting a transplant, the mean time between initiation of ESRD service and entry on transplant registry or commencement of preparations for a LRD transplant was 6.97 months.

87.10% of these patients were entered on a registry or preparations were started for a LRD transplant within 1 year of initiation of ESRD service.

41 patients, 35.04% of the sample population are not currently candidates for transplant.

FINANCIAL INFORMATION

- Medicare Status

Medicare covered	70.94%
Medicare applicant	23.08%
N/A	5.98%

- Payment of Coinsurance and Deductible

Medicaid only	18.80
Title V only	3.42
Private or group insurance only	41.88
Medicaid & Title V	17.09
Title V and private insurance	3.42
Medicaid & private insurance	2.56
Medicaid, Title V, & private insurance	3.42
N/A	9.40

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Chairman RANGEL. Thank you, Doctor.

The Chair would like to announce that because many members are involved in the discussions on the budget, including the Chair, we will be forced to recess at 12:15 and resume at 1 o'clock. And I say that for the consideration of patients—I mean [laughter] for witnesses who have not yet testified.

I assume that all of you are saying that hospitals that provide additional medical services that the costs for those services should be taken into consideration, and when you do provide training for home dialysis then certainly somehow that should be reimbursed, and hospitals should not be penalized.

You are not saying, doctor, that included in the reimbursement should be tuition payments for medical students, are you?

Dr. THOMPSON. My medical students would love it, but I am not suggesting we pay their tuition.

Chairman RANGEL. Could you explain what you mean? Those hospitals which have affiliations or contracts with educational institutions, I thought you said there is $12 worth of training for the student.

Dr. THOMPSON. That is right. In a teaching hospital where you have programs to train, not just medical students but house officers, nurses, dialysis technicians, you are talking about increasing the cost of all of the treatments in the hospital. These are medicare allowable increases in costs.

As a matter of fact, they cost about $12 per dialysis. We try to allocate dialysis for its share of the overall training in the teaching hospital. This is not a tuition. This is what it costs to have an intern or a resident, a fellow involved.

Chairman RANGEL. But if this type of training is not going on in the free-standing clinic——

Dr. THOMPSON. That is right, it is not. In other words, interns and residents, renal fellows, who are specializing in those areas.

Chairman RANGEL. What does that have to do with patient treatment?

Dr. THOMPSON. Those people also provide care to my patients. The renal fellows are there because these patients are unstable. Those people are on call in the hospital all of the time.

Chairman RANGEL. I would assume that you would know best as to who could provide treatment to the patient and whether it is a resident or a nurse. That is none of my business.

But do not your people get paid for providing that service? They may not get paid enough, but they are not doing it free.

Dr. THOMPSON. They are not doing it free. But it costs the Government, if the Government is paying for the dialysis. In my unit they are paying $12 a dialysis for that. Under the proposed regulations, if there are no exemptions you will not be paying for that, or a whole lot of other things available at my hospital and others.

Chairman RANGEL. I see.

Do any of the witnesses believe that where there are treatment facilities for patients who do not have additional problems, but just need dialysis, that it should not be done in the hospital if they have access and can be treated at other places with less costs, without the overhead of hospitals?

Dr. **Capelli**. Yes, I think that is certainly the case, and I think the experience in the program has shown that over the years, with the growth of the independent facilities. You have a large population.

Chairman **Rangel**. Yes. But the hospital associations would generally agree that they should have the type of patients that need, for one reason or another, a hospital setting, and that where you can get less expensive treatment for patients who do not need the hospital setting, that if we could find a way to encourage that we should.

Dr. **Thompson**. I think you could at least get agreement, Mr. Chairman, that the hospital dialyzing the stable patient should only get paid as much as a free-standing facility for dialyzing that stable patient. The only increase in payments to hospitals would be for the care of unstable patients and patients with special needs, like pediatric patients.

You might find some hospitals who would object strongly to saying their patients have to go to free-standing facilities because the hospital facility may be the sole dialysis unit in the area or may traditionally have provided the service.

Chairman **Rangel**. So what you are saying is the hospital should have to prove their case as to why this patient required more than a regular dialysis?

Dr. **Thompson**. I would agree with that, but there would have to be definite criteria. You cannot just say it vaguely compared to something that does not exist. I think there should be specific indications for proving the patient is less stable.

Chairman **Rangel**. All I am asking is, can you people devise some kind of a way to show that you are not taking care and being reimbursed for patients who do not need all of the overhead costs that hospitals necessarily would have to have with or without dialysis patients? You would have to take care of those residents anyway.

Dr. **Thompson**. I think we could demonstrate the difference between different kinds of admissions.

Chairman **Rangel**. You cannot do that?

Dr. **Capelli**. I think it is difficult. If you have a six-bed dialysis unit in a hospital that provides in-patient dialysis care for the patient with current illness and that unit is also used to support some of the chronic ambulatory dialysis patients as exists in this country, some of those patients will be unstable patients, as referred to. But some will be chronic ambulatory dialysis patients who are generally stable.

I think it is difficult to totally separate out and identify those patients for the purposes of reimbursement. I think it will be a horrendous problem for the intermediaries to do that.

Chairman **Rangel**. How do we answer some people who may believe that those patients need services, but they really do not need the type of overhead hospitals cannot get away from?

Dr. **Capelli**. I think the problem of hospital cost allocation is something that has been abused to some extent by hospitals, and I think that there are methods available to the hospitals and to intermediaries to control those allocations of costs. One of the things that has happened, Mr. Rangel, in this medicare ESRD program in terms of allocation of costs, because medicare is 100 percent payor for dialysis, virtually 80 percent of indirect costs which are allocations from a dialysis unit are picked up by medicare, whereas the hospital's total indirect costs may be only 30 percent allocated to medicare.

It just happens to be a quirk of the system because medicare happened to be 100 percent payor for that service. So I think there can be some provisions made to accommodate the methodology in which indirect costs are allocated to dialysis units in hospitals.

Chairman **Rangel**. Doctor, you have to participate on this analysis of how to do it.

Dr. **Capelli**. We have tried to do that.

Chairman **Rangel**. Because so often we hear—well, you are church-affiliated, but we hear from——

Dr. **Capelli**. From other people. Other people are honest, too.

Chairman **Rangel**. There is a connection between Catholic hospitals and the church, I hope?

Dr. **Capelli**. It is getting less and less.

Chairman **Rangel**. Certainly both of you would agree to that. [Laughter.]

But you have to be able to provide real answers to legislators making hard decisions how to cut costs. If you want to avoid people just across-the-board cutting, then you as doctors and surgeons have to come up with some realistic answers as to how the reimbursement system is not fair.

But you are not going to be able to override the decisions others have made if it must be done by a cleaver, the way it was done last year.

The tragic thing is your clientele cannot live without the services and other people will merely suffer. I do hope, as you hear the administration this afternoon—we do not have confrontation for confrontation's sake—that you do try to work with the administration and try to make it as nonpartisan as possible, to make certain that the patient is protected, but the reimbursement system is not one that is going to help some vested interest more than the patient.

And that is very difficult. I do not know how to do it. I am not getting involved with doctor-patient relationships, nor am I getting involved with the corporate structure. It is hard for me to understand why—except in the area of public hospitals; they should be paid more because they are public hospitals. But private hospitals, it is very difficult to explain to the nonprofessional as to why people should be paying for all of your overhead when the patient does not need it.

Now, if you are talking about 6 or 7 beds or 10 or 12 patients, I can understand it may cost more to evaluate. But you are involved in the business and we are not. We are involved in trying to protect the consumer, the constituent, the patient.

So in order to make it fair we have to rely on your professional judgment, as well as your code of ethics, and we have to hammer out how we can take care of all of those considerations.

Mr. Martin.

Mr. **Martin**. Thank you, Mr. Chairman. I will be brief.

I recall in an earlier discussion with Dr. Thompson that the point was made that many hospitals have higher costs than free-standing facilities, because they have a higher degree of home dialysis patients, and, that those facility costs in the past have contributed to the overall hospital cost being higher. And we discussed the utilization of the new separate fee for home dialysis patients being chargeable by the hospital.

In another area, we have heard that pediatric dialysis generally is higher for various reasons. Mr. Bland suggested a separate rate for that. Is that a reasonable suggestion? Are you in agreement with that, that there should be a separate rate for pediatric dialysis?

Dr. **Gruskin**. Yes; that is one of the suggestions that I made.

Mr. **Martin**. I am sorry, I stepped out of the room while you were making your statement.

Is there a catalog of other factors that ought to be treated by a separate rate? Is that really where we ought to be going, a catalog of rates?

Dr. **Fortner**. Probably the home dialysis training program should be addressed specifically, because the rates being paid for training have consistently been below cost. That presents a burden to the hospitals who have been doing the training.

Mr. **Martin**. Any others? Any other complicating factors?

I presume, Dr. Thompson, when you were discussing the patients with complications and the reasons why the freestanding unit has a limitation on those kinds of patients being accepted, and, the fact that those types of cases therefore are being treated at your hospital, you discussed those as being treated in your outpatient clinic because your inpatient care would have separate itemization of costs, whereas your outpatient care does not?

Dr. **Thompson**. That is right. The inpatient care is itemized separately. It does not come under the same types of regulations as the outpatient.

Mr. **Martin**. And it does not involve the same burden of justification?

Dr. **Thompson**. Yes, but there clearly are patients who are capable of being at home, not having to be in the hospital. And there are those who are still quite unstable when it comes to the dialysis procedure.

Mr. **Martin**. Would you also want your outpatients to have their billing done on an itemized basis?

Dr. **Thompson**. I think there has to be some system for taking care of the patient that requires a 1-to-1 patient ratio versus a patient who can be dialyzed in a setting where there is one staff person for every four patients. Obviously it will cost more and there must be some way to pay for that type of a patient.

Mr. **Martin**. Thank you.

Chairman **Rangel**. My last question to the panel is, I got the impression from listening to Dr. Thompson that in many of the self-standing clinics they may have a criteria for evaluating the health of the patient, the attitude of the patient, and that they make a determination whether they are going to take that patient or not. Is that what you were saying?

Dr. **Thompson**. Yes, I was.

Chairman **Rangel**. Do hospitals do the same thing?

Dr. **Fortner**. Mr. Chairman, in the area of northern California where our facility exists, the independent facilities belong to a nonprofit, a single nonprofit organization, and they have very specific criteria for admitting patients. And if patients become unstable in that setting, they, by determination of the head nurse or the medical director, not the patient or the patient's physician, insist on that patient being returned to an in-center facility in the area.

Chairman **Rangel**. Well, you see, I am trying desperately hard to stay out of the doctor-patient relationship. But it is my understanding that some of these things are not related to the health of the patient. It is the attitude and the cost factor involved, and that hospitals cannot make that determination.

Is it possible for you hospital people to sit down with the private sector and try to work out some criteria? I mean, rather than—if a healthy patient gets in a fight with a healthy patient, then they go to the hospital.

Dr. **Thompson**. If the healthy patient gets into a fight with another healthy patient, they may be given the opportunity to go find another free-standing center.

Chairman **Rangel**. Suppose there is no free-standing center around and they end up at your hospital with a note? [Laughter.]

Dr. **Thompson**. This is exactly what will happen. They will either arrive at my hospital with a note or they will not be dialyzed for a period of time if they were discharged from the center, and they would wind up in an emergency room requiring an emergency dialysis and after the crisis I wake them up and find out how sick or difficult they are to deal with and that no one else wants them.

So what do I do? Say, you have an unpleasant personality, therefore we can't treat you so you will die? No; I wind up dialyzing the patient.

Dr. **Fortner**. The law prevents us from doing that any longer.

Dr. **Thompson**. Yes; we are not allowed to refuse patients because we do not happen to like them. So, yes, we can get stuck much more easily with those types of patients.

And Mr. Chairman, I think the other point to make is, it is not unreasonable for the free-standing center to have specific rules and regulations about what types of patients they think are safe to dialyze in their units, what types of patients will allow them to operate efficiently. That is their role. There are patients who are dialyzed in my unit that I would consider for a free-standing center. But the center that takes that patient may not feel that the person has any great concern with safety.

Chairman **Rangel**. I do not argue with that, doctor. But a person who curses should not be kicked out of a self-standing clinic. There are some limitations as to how pleasant the surroundings can be. It is not a very pleasant thing, generally.

So I am just hoping that as much of these things that we do not know about that you people can handle, the less Government and political involvement we will have. And we have our hands full with the budget process. This is just a little much.

Thank you, and let me say before I adjourn that if there are people here who will not be testifying, recognizing how complex it is, if you have questions that you do not believe have been covered by the members or the witnesses, feel free to write those questions out and give them to staff. I do not know whether they will be handled, but I will guarantee that they will reach the proper regulatory authority.

The committee will adjourn until 1 p.m.

[Whereupon at 12:15 p.m., the committee was recessed, to reconvene at 1 p.m. the same day.]

AFTERNOON SESSION

Chairman **Rangel**. The hearings will resume.

I understand there is a problem here with Dr. James Cerilli, the past president of the American Society of Transplant Surgeons. If he wants to take this time to submit his testimony, he can do that.

Doctor?

STATEMENT OF JAMES CERILLI, M.D., PROFESSOR OF SURGERY, OHIO STATE UNIVERSITY, AND PAST PRESIDENT, AMERICAN SOCIETY OF TRANSPLANT SURGEONS

Dr. **Cerilli**. Thank you, Mr. Chairman. I am Dr. James Cerilli, currently professor of surgery at Ohio State University and past president of the Ohio State Society of Transplant Surgeons. This is a group of academic surgeons, a society in support of education and research.

Your committee, Mr. Chairman, has a difficult task. It is a challenge, really, to try to improve medical care in a difficult area and to do it with less money. I am not here to comment on the merits of the specifics of this reimbursement proposal, but rather to comment that I think that if this composite system is implemented, rather than costs going down, I think there is a substantial chance that costs will go up, and I will tell you the rationale for that.

My purpose today is twofold: First, I want to call your attention to recent improvements in transplantations which impact on the conclusions I have drawn today. I would like to share with you the reasons for our serious concern over the proposed dialysis reimbursement regulations and our recommendations for a more reasonable and cost effective payment methodology for services to patients with end-stage renal disease.

Transplantation has made some enormous strides in the last few years, and this impacts enormously on the decision you need to make. The mortality rates in transplantation have dropped very dramatically in the last 2 or 3 years. The chance now of dying as a result of a transplant is less than about 4 percent.

Risk of the operation itself to the patient has gone down very dramatically, since in the last 200 transplants we have done at Ohio State we have had only 3 deaths. So it has gone down very much over the last few years.

Second, graft survival rates have improved dramatically, so that with a living related donor—and I think this is important to the discussions today—the recent experience in San Francisco and other places is that 95 percent of these transplants are working. And with cadaver donors, we are talking about 65 to 70 percent survival.

These are important figures because they impact very closely on the decision you make today. It is also worth reminding everyone that when a patient gets successfully transplanted the rehabilitation rates are about three times that of a dialysis program. It is well documented in the literature, about 75 to 80 percent of these patients are rehabilitated.

The cost savings for transplantation over dialysis have also been well documented and are on record in many hearings such as this before congressional committees. For instance, if you transplant 100 patients as compared to dialyzing them for 10 years, you save $15 million, not counting the savings really from rehabilitation.

Because transplant surgeons are actively engaged in the medical management of renal disease patients, we are greatly concerned about what we believe to be the adverse impact of the proposed Health Care Finance Administration dialysis program. In our opinion, this is medically counterproductive and fiscally irresponsible. We strongly urge the regulations be withdrawn and revised.

Since the inception of the ESRD program, the principal objective has been the promotion of transplantation for medically suitable patients. All of the networks and numerous Government agencies and reports have endorsed the goals related to the appropriate referral of patients for transplant evaluation.

Mr. Chairman, it is my belief that the proposed payment method will produce results the opposite of its objective. It will create an enormous financial disincentive for referral of patients to transplantation and further promote the sequestration of programs in dialysis centers.

While the proposed composite rates are intended to create incentives to promote home dialysis, it is more likely the rate structure will prompt dialysis centers to recruit and maintain patients who are dialyzed at home. By enrolling and retaining such patients, centers, both hospital and free standing, can alter their mix of patients and thereby improve their financial condition.

It is generally recognized that the portion of renal disease patients on home dialysis includes some of the most promising candidates for successful transplantation. Paying the same rate for infacility and home dialysis means that this group of patients will provide dialysis centers with reimbursement substantially above costs. It is unlikely, therefore, that referral to transplantation will be aggressively promoted.

The loss of patients on home dialysis to transplantation would adversely impact on the financial condition of the center. The perverse incentives I have described really do not sound to me like sound public policy.

We have been seeking various approaches for assuring that the reimbursement system for renal disease care does not bias the choice of therapy which is medically appropriate. We believe the payment system for ESRD services should be based on the principle that patients should have an incentive to seek the most cost effective therapy consistent—and I emphasize that, consistent—with their medical condition.

In order to establish such a payment system, one can say that all patients under the age of 50, upon achieving eligibility in the ESRD program, should be presumed to be medically suitable for transplantation and referred to appropriate consultation. In the case of this subset of renal patients, if the attending physician makes a determination that referral is not indicated because transplantation is not medically appropriate, the patient should be evaluated by the appropriate renal network review committee. The purpose of these procedures is to provide medicare with independent medical judgment concerning the reasonable and necessary care and therapy which should be covered by the program.

Parenthetically, I would add that this is a problem. I can draw data from our own network that shows that in network 22 at this point in time there are over 1,100 patients under the age of 50 who are not on transplantation lists. Now, some of these are not medically suitable, but certainly not all of them.

Pending a decision by the patient and the availability of a suitable donor kidney, dialysis services would continue to be covered as under current policy for patients on the transplant list. Of course, patients who are not found to be suitable for transplantation or who experience rejection of grafted kidneys would have payments for dialysis continue by medicaid. Medically suitable candidates for transplantation, as determined by a medical review board, who choose not to seek transplantation should face some limit on the extent of coverage for dialysis services which would be covered by medicare. The added cost of care resulting from an unwise patient choice should not be part of a reasonable cost or charge recognized by medicare.

We believe this approach to the evaluation, treatment and reimbursement of patients suffering from end-stage renal disease is reasonable, fair, and cost effective. It would assure that all patients are evaluated on the basis of medically established criteria and counseled concerning the most appropriate form of therapy.

Most importantly, it would extend the medicare policy concerning payment for only reasonable and necessary medical services to the ESRD program. And it would provide an incentive for patients to elect the most cost-effective form of therapy consistent with their medical condition.

Unless we are willing to significantly restructure the reimbursement system of the ESRD program, we will continue to see an exploding growth in the expenditures for services to these patients. Promotion of cost-effective forms of kidney dialysis must not be at the expense of timely and appropriate referral for transplantation.

I am sure that the individuals who have put together this proposed composite reimbursement system did so with the good faith that this would lead to decreased cost of the program. I am afraid they did not consider the subtleties of referral patterns within the ESRD program, and the impact that the cost disincentives would have on the referral of patients.

Transplantation is clearly more cost effective and there should not be a cost disincentive or financial disincentive to referring patients into this form of therapy. Our proposal, then, really is to support the position that these regulations be withdrawn and significantly revised, and that the new regulations take into consideration the impact of referral of patients to a medically suitable and cost effective form of care—transplantation.

[The prepared statement follows:]

STATEMENT OF THE AMERICAN SOCIETY OF TRANSPLANT SURGEONS PRESENTED BY JAMES CERILLI, M.D.

Mr. Chairman, I am James Cerilli, M.D., professor of surgery in the renal transplant program in the Department of Surgery of The Ohio State University, the immediate past president of the American Society of Transplant Surgeons, and recently appointed Chairman, Department of Surgery, Albany Medical Center, New York. We appreciate your invitation to the Society to participate in these hearings and we are anxious to be of assistance to the Committee as you consider the issues surrounding the recently proposed reimbursement regulations for renal dialysis services.

My purpose today is two-fold. First, I want to call your attention to recent and dramatic advancements in renal transplantation which have not been widely reported. Second, I would like to share with you the reasons for our serious concern over the proposed dialysis reimbursement regulations and our recommendations for a more reasonable and cost-effective payment methodology for services to patients with renal disease.

In many cases progress in medical care is not rapidly reported or fully understood. This is certainly the case in the field of renal transplantation. In a study of eight large university transplant centers conducted in 1979 by the Society, living related donor graft survival rates at one year were 75 percent and cadaveric graft survival rates were 55 to 60 percent. That means that not only was the patient alive but the transplanted kidney was performing satisfactorily. Mortality rates at one year were less than 10 percent for this severely ill population. Thus, the mortality rate, not only from surgery but all other factors is comparable to that of patients on dialysis.

Even more recently, with the introduction of donor-specific transfusions, graft survival rates in patients receiving living related donor kidneys in such centers has increased to 95 percent while cadaveric graft survival rates have increased to between 65 and 75 percent. In such large academic medical centers mortality rates are well below 5 percent. In my own institution, mortality rates for non-diabetic patients under 55 on chronic dialysis actually exceeded the mortality rates for transplanted patients. We expect continuing progress through promising developments in research which are being transferred into clinical practice.

Furthermore, renal transplantation is significantly less costly than any form of dialysis. The current cost of a renal transplant is approximately $20,000 to $25,000 during the first year and approximately $1,000 per year afterwards. In contrast the cost of chronic center hemodialysis plus hospitalization for complications averages about $28,000 annually. These savings figures do not include the effects of successful transplantation on the rehabilitation of ESRD patients. Studies at three university transplant centers reveal that approximately 75 to 80 percent of transplant patients return to an occupational activity equal to or exceeding that prior to their illness and thus reduce welfare and social security costs and increase tax revenues compared with those continuing on dialysis. According to a study published recently in The New England Journal of Medicine, less than one third of patients on chronic hemodialysis at Duke University Medical Center were able to maintain themselves independent of support.

Because we are actively engaged in the medical management of renal disease patients, we are greatly concerned about what we believe to be the adverse impact of the proposed Health Care Financing Administration (HCFA) dialysis reimbursement rates. In our opinion this proposal is medically counter-productive and fiscally irresponsible. We strongly urge that the regulations be withdrawn and revised.

Since the inception of the ESRD program a principal objective has been the promotion of transplantation for medically suitable patients. All of the renal networks and numerous government agencies and reports have endorsed goals related to the appropriate referral of patients for transplantation evaluation. Mr. Chairman, the proposed payment method will produce results which are the opposite of this objective. It will create an enormous financial disincentive for referral of patients to transplantation and will further promote the sequestration of patients in dialysis centers.

The reasons for this are quite apparent. It takes effort and staff time to counsel patients and refer them for consideration for transplantation. There is to be no compensation for this effort. Rather, from the center's perspective if it is successful, it will result in a loss of revenues. In fact, while the proposed composite rates are intended to create incentives to promote home dialysis, it is more likely that the rate structure will prompt dialysis centers to "recruit" and maintain patients who are dialyzing at home. By enrolling and retaining such patients, centers (both hospital and free-standing) can alter their mix of patients and thereby improve their financial condition.

It is generally recognized that the portion of renal disease patients on home dialysis include some of the most promising candidates for successful transplantation. Paying the same rate for in-facility and home dialysis means that this same group of patients will provide dialysis centers with reimbursement that is substantially above costs. It is unlikely, therefore, that referral to transplantation will be aggressively promoted. The "loss" of patients on home dialysis to transplantation would adversely impact on the financial condition of the center. The perverse incentives I have described do not strike me as sound public policy.

We in the Society have been seeking various approaches for assuring that the reimbursement system for renal disease care does not bias the choice of therapy which is medically appropriate. We believe that the payment system for ESRD services should be based on the principle that patients should have an incentive to seek the most cost-effective therapy consistent with their medical condition.

In order to establish such a payment system, all non-diabetic patients under the age of 50 upon achieving eligibility in the ESRD program should be presumed to be medically suitable for transplantation and referred for surgical consultation by their attending physician. In the case of this subset of renal patients, if the attending physician makes a determination that referral is not indicated because transplantation is not medically appropriate, the patient should be evaluated by the appropriate renal network review committee. The purpose of these required procedures is to provide Medicare with independent medical judgment concerning the reasonable and necessary care and therapy which should be covered by the program.

Pending a decision by the patient and the availability of a suitable donor kidney, dialysis services would continue to be covered as under current policy for patients on the transplant list. Of course patients who are not found to be suitable for transplantation or who experience rejection of grafted kidneys would have payments for dialysis continued by Medicare. Medically suitable candidates for transplantation (as determined by a medical review panel) who choose not to seek transplantation should face some limit on the extent of coverage for dialysis services which would be covered by Medicare. The added cost of care resulting from an unwise patient choice should not be part of a reasonable cost or charge recognized by Medicare.

We believe this approach to the evaluation, treatment, and reimbursement of patients suffering from end stage renal disease would be reasonable, fair and cost-effective. It would assure that all patients are evaluated on the basis of medically established criteria and counseled concerning the most appropriate form of therapy. It would extend current Medicare policy concerning payment for only reasonable and necessary medical services to the ESRD program. And, it would provide an incentive for patients to elect the most cost-effective form of therapy consistent with their medical condition.

Unless we are willing to restructure the reimbursement system of the ESRD program we will continue to see an exploding growth in the expenditures for services to these patients. Promotion of cost-effective forms of kidney dialysis must not be at the expense of timely and appropriate referral for transplantation. Our proposal is not fully developed or set in concrete. We are anxious to work with you and your staff and others to refine it.

To summarize, Mr. Chairman, we are convinced that the proposed dialysis reimbursement regulations will inhibit the referral of patients to transplantation. It will further exacerbate the sequestration of patients in chronic dialysis centers. We doubt also whether it will actually promote more home dialysis since the incentive is greater for centers to enroll patients who are already dialyzing at home than to take on the troublesome task of training new patients for home dialysis. Therefore, the proposed regulations should be withdrawn.

Mr. Chairman, we want to thank you for this opportunity to participate in these hearings. I would be happy to respond to any questions you or other members may have.

American Society of Transplant Surgeons,

May 11, 1982.

Hon. Charles B. Rangel,
Rayburn House Office Building,
Washington, D.C.

Dear Mr. Chairman: I thought it might be helpful to explain further one of my concerns related to a matter I alluded to in my testimony before your Oversight

Committee in its hearings on the proposed reimbursement regulations for end-stage renal disease.

My concern is that the proposed regulations which are intended to conserve funds do nothing—in fact are probably counter-productive—to advance the change in treatment of renal patients which would, in my opinion, constitute the most effective way to reduce program costs and improve the quality of life of patients. I am referring to the desirability of sharply increasing the portion of patients who are treated by transplantation. A transplanted patient can be restored to a much more normal and productive life than can a patient on dialysis.

There are a number of barriers in the way of this treatment change. It seems to me that one of the most significant barriers to it results from the fact that patients who suffer end-stage renal disease must immediately go on dialysis in order to sustain life. Thus, the initial treatment of such patients is likely to be in a facility providing dialysis and by a physician who specializes in caring for patients on dialysis. The patient whose life is sustained by dialysis and whose orientation to treatment is provided by facilities and physicians specializing in dialysis may not be fully exposed to the relative merits of alternative approaches.

I believe that there are actions that Medicare can and should take to overcome this difficulty. Provisions can be added to the program to encourage referrals or to penalize with reduced reimbursement facilities or physicians supervising the care of renal patients who fail to refer appropriate patients to qualified surgeons to assess their suitability for transplantation.

Another corrective step would be to assure that patients do not refuse to consider the possibility of surgery. A provision could be incorporated in the program similar to one which has been applied otherwise in the Social Security disability program. The disability program defines the circumstances under which disability benefits will not be continued where the disability is remediable. The law provides for suspension of disability benefits to enforce the acceptance of appropriate rehabilitation services. The disability provision has not been applied harshly but rather with recognition of the patient's rights and personal views. In fact, the provision takes into account psychological, religious and medical factors in its administration by the Social Security Administration. The regulations do permit exceptions to the policy when the prescribed care involves unusual or highly risky procedures. It is not clear whether kidney transplants are now included among the required remedies, but it is clear that they should be so classified.

We believe a similar approach should be taken in applying Medicare rules related to the reasonableness of medical care provided under the ESRD program. I think the remediability provision that is applied in the case of disability beneficiaries has had the value that it requires the patient to consider carefully the possibility of remedy. In fact, as I previously mentioned, it is possible that this provision of disability law already applies to end-stage renal disease patients who are in receipt of disability benefits. In any event, reliance on the remediability policy of the disability program would help to establish the point in the mind of patients and the population generally that transplantation is, in the view of the government, the preferred treatment in the case of patients for whom it is appropriate. This policy is certainly consistent with exiting Medicare law which limits payments under the program to care which is found to be reasonable and necessary. Treating a patient in an excessively costly fashion and in a way that produces a lower quality of life than is possible does not seem reasonable and necessary.

We believe that if the incentives for transplantation and proper information to patients and the general public are developed, additional donation of organs would also be encouraged. We would suggest strong action to maintain the standards of transplantation at the level of the many highly qualified centers that now exist so that the patients provided transplants would be assured that the potential success of transplantation is at the maximum rate. This combination of actions could be far more beneficial to the ESRD program than the proposed dialysis reimbursement rates.

Sincerely,

James Cerilli, M.D.,
Past President.

Chairman Rangel. Are you saying you do not want to encourage too much home dialysis because among those people would be included a lot of good candidates for transplantation?

Dr. Cerilli. Yes. The patients who are good for home dialysis are usually also excellent transplant candidates.

Chairman **Rangel**. So you do not want them at home because you do not believe that people will refer them to the surgeons?

Dr. **Cerilli**. What I am saying is there will be a financial reason not to put them into transplantation.

Chairman **Rangel**. So doctors will decide what is in the best interest of the patient based upon how many dollars they are going to get?

Dr. **Cerilli**. That is part of the issue, and also the financial solvency of individual units.

Chairman **Rangel**. And you are further saying, after a group of doctors get together and find out what is best for the patient and they conclude it is transplantation and the patient says, you may be right but I do not want to go that route, they should be penalized financially?

Dr. **Cerilli**. I am saying they should have a limitation on how long the medicare program, which is charged with providing reasonable and necessary care—they should have a limit on the longevity of the medicare coverage.

Chairman **Rangel**. What did I say that you differ with?

Dr. **Cerilli**. Nothing. [Laughter.]

Not a thing. But I am saying, until there is a stimulus originating from the patient to seek cost effective forms of therapy, it will be extremely difficult to accomplish that goal.

Chairman **Rangel**. Thank you.

The next panel will be: Dr. Constantine Hampers, chairman of the board, National Medical Care, Inc., Boston; Robert Green, chairman of the board, Community Psychiatric Centers, San Francisco; and Dr. Christopher Blagg, director, Northwest Kidney Center, Seattle, Wash. Your full statements will appear in the record.

Hi. Good to see you again.

Dr. **Blagg**. Hi.

Chairman **Rangel**. When you had me out there in Seattle telling me about home dialysis, you did not tell me there were all these problems with home dialysis.

Dr. **Blagg**. I knew other people would tell you about the problems. [Laughter.]

Chairman **Rangel**. Dr. Hampers?

STATEMENT OF TIMOTHY I. McFEELEY, VICE PRESIDENT AND CORPORATION COUNSEL, NATIONAL MEDICAL CARE, INC.

Mr. **McFeeley**. My name is Tim McFeeley. Dr. Hampers has asked me to give the statement for National Medical Care, Inc. this afternoon.

Chairman Rangel, as I said, my name is Timothy McFeeley and I am here today to present the views of National Medicare Care, Inc. I serve as vice president and corporation counsel. We appreciate this opportunity——

Chairman **Rangel**. Mr. McFeeley, you have a rather lengthy statement.

Mr. **McFeeley**. I do not intend to read the full statement.

Chairman **Rangel**. I want you to know that the full statement will appear in the record.

Mr. McFeeley. We believe the Government should pay a single rate for the same service, with adjustments for area wage differentials. Clearly, the burden of proof is upon those who contend that a hospital should be paid more than an independent facility in the same county for an identical service.

The data produced at a recent hearing of the House Subcommittee on Intergovernmental Relations and Human Services to the effect that the frequency of hospitalization may be lower for patients of independent centers than hospital-based dialysis centers does not sustain the burden. Higher hospital rates are predictable for hospital-based patients not because they are sicker than their counterparts in the free-standing facilities, but because of physician convenience, institutional pressure and inadequate dialysis, particularly among CAPD patients, most of whom are hospital-based patients.

We concur with the Department's statements on 6564 of the NPRM to the effect that there is no justification for hospitals to pay more for supplies than independent facilities and that there are no data that support the claim that hospital patients require a higher degree of care than patients of free-standing centers.

The inability of the Department to hold the line on patient exception requests and to prevent the kidney program from sliding into the wasteful cost-reimbursed quagmire has resulted in justifiable public and congressional concern. In this program exceptions do not prove the rule; exceptions are the rule.

The Government and coinsurers are paying hospitals on the average more than $174 for a dialysis service the independents provide for $138. That is a difference of over $36 a treatment or $139 million this year.

The Department's proposal to set a rate nearly identical for both hospitals and independents and to restrict exceptions to the exceptional is rational and cost efficient. We also believe by setting an adequate single rate program costs can be cut by $75 to $90 million.

Believing that home dialysis is less costly than in-center dialysis, Congress has directed HHS to devise a composite rate providing a financial incentive for the facility to send patients home. We accept this composite methodology, provided that the data used in setting the composite rate, both with respect to relative costs and with respect to relative percentages of the use of each mode of therapy are accurate.

In addition, the home rate should be standardized. It is absurd to suggest that medicare pay more for patient Jones dialyzing at home in apartment 2A than for patient Smith in apartment 2B because Jones is a hospital-based patient.

We believe the composite methodology will not increase the use of home care and predictions by HHS that 30 to 40 percent of all U.S. dialysis patients could be treated at home are insupportable, especially in light of the dismal CAPD results which I will discuss in a moment.

The cost of home dialysis would be equal to or greater than the cost of efficient in-center care if we added the cost of a paid assistant and increased hospitalization associated with home care. When HHS compares $97 with $126, it is not comparing home care versus in-center care, but rather self-care versus staff-assisted care. The $30 difference very nearly equals the cost of a paid assistant on a 5 to 6-hour duty. Therefore, the cost saving projected in the composite methodology is simply the cost shift from the center to the patient and his or her family.

Chairman RANGEL. What page are you on, doctor?

Mr. McFEELEY. I am on page 4 of the larger typed version, not that one, sir.

Chairman RANGEL. Do we have a copy of that?

Mr. McFEELEY. It is a briefer version.

There is simply no evidence to suggest that 40 percent of dialysis patients can count on a family member or friend who is capable and available to provide this free service. With respect to nonlabor costs, note that home dialysis is 27 percent more expensive than free-standing center care.

Home dialysis is simply not appropriate for all patients. It requires a relatively healthy patient in a middle class environment. If we restrict dialysis to the young, healthy and middle class, we might attain the HHS goal of 40 percent on home therapy. Fortunately, Congress has always mandated that dialysis care will be available to all patients, and this means we have to expect fewer home patients as a percent of the dialysis population.

A special comment is in order concerning continuous ambulatory peritoneal dialysis. Recent data from Government-financed studies indicate that CAPD results are dismal. An astounding 84 percent of patients who begin CAPD were hospitalized within 9 months after commencement of the therapy, and the average annual hospitalization rate for CAPD patients is nearly double that of other dialysis patients. Moreover, after one year on CAPD over half, or 57 percent, of these patients dropped out of CAPD due to death or abandonment.

European and Canadian studies are similarly disconcerting. These data compel the Department to reassess its proposal to pay for CAPD therapy except in unusual cases. HHS should definitely retract any encouragement of this form of therapy.

In addition, the composite rate should be recomputed to discount the inflated home dialysis percentage attributed to CAPD or portable dialysis, as it is now being marketed by one supplier.

The Department's proposed methodology to establish a single composite reimburseable rate for dialysis makes sense. The data used, however, in setting the national average rates at $132 for hospitals and $128 for independents are unreasonable and will result in severe cutbacks.

First, with respect to both hospitals and independents the cost data are 4 or 5 years old. Yet no adjustments are made for inflation. The 1982 NPRM uses the data collected in 1980 for an earlier discarded proposal. I need not remind you that Congress has mandated a prospective rate, not one looking back at 5 year old data.

Second, with respect to most independent facilities HHS has excluded roughly 15 percent of actual costs, or approximately $20 per treatment. It seems incredible, but many of these excluded expenses, such as bad debts and return on equity, would have been medicare reimbursed even under part A cost reimbursed system.

Other expenses, such as executive compensation and physician office costs, were eliminated as unnecessary or excessive.

HHS does not argue that these costs were not incurred by the independent facilities. Therefore, when HHS tells you that the cost of providing dialysis services by independents is only $108, please note that the number is 5 years old and does not include costs such as return on equity, bad debts, certain executive compensation and stockholder maintenance costs, without which the independents simply could not stay in business.

Third, the home dialysis costs are understated because the audit sample included only the most efficient home programs, were weighted by the number of treatments performed, and ignored the higher cost of supplying home patients whose charges are not billed through a center. In addition, the home dialysis percentage used in the composite rate calculation includes CAPD patients.

HHS admits the $132 and $128 rates will under-reimburse 46 percent of the hospitals and 28 percent of the independents. If more recent and complete data were used, the impact would be much higher. We believe the proposed rates will under-reimburse over one-half of all facilities, and this enormous impact is simply unacceptable. It will clearly jeopardize access to care to which all dialysis patients in the United States are entitled by law.

We believe quality care for all dialysis patients can continue to be provided at lower overall program costs by eliminating exceptions and reducing the reimbursement rate from the present average rate of approximately $160 per treatment. For example setting an average single rate of $150 per treatment would save about $90 million per year.

National Medical Care facilities provided nearly 1½ million dialysis treatments last year and the quality of that service was exemplary. Moreover, we provide a service at the lowest cost to the Government. The company has saved the Government millions of dollars through privately financed expansion, replacing costly hospital care with efficient in-center and home care.

The ESRD program has benefited from NMC's efforts to improve dialyzer efficiency, reduce dialysis time, improve patient to staff ratios, reduce costs through reuse of dialyzers, and to enhance efficiency through innovative systems. To be sure, we have made profits and paid taxes on those profits. As a proprietary corporation, if we did not make profits we simply would not exist.

The ESRD program is the best example I know to illustrate the proposition that Government can improve the lives of the people. The ESRD program has literally saved thousands of lives, lives that are lost in less compassionate, less resourceful nations. The present attempt by this Congress and administration to eliminate waste and make the program more efficient is an endeavor in which National Medical Care will cooperate with labor and all of the resources at our disposal.

Thank you, Mr. Chairman.

[The prepared statement follows:]

STATEMENT OF NATIONAL MEDICAL CARE, INC.

As the nation's largest provider of kidney dialysis services, National Medical Care, Inc. ("NMC") appreciates this opportunity to express its views on the Medicare End-Stage Renal Disease ("ESRD") Program before this House Subcommittee charged with overseeing the administration of the Program. We hope that the testimony of NMC, along with the testimony of other providers of care, patient representatives and administration officers charged with managing the Program, will assist this Subcommittee in determining how well the Congressional objectives of adequate medical care for all Medicare beneficiaries disabled by irreversible kidney failure and economical delivery of care at the lowest cost to the public treasury are being met.

We address our comments to these questions: Has the Medicare ESRD Program provided life-saving care to all eligible kidney patients in an efficient, cost-conscious manner? Will the changes in the ESRD Program recently proposed by the Department of Health and Human Services ("HHS") improve the Program with respect to these Congressional goals?

The comments are organized to review the background and accomplishments of the ESRD Program since its inception in 1973, the strengths and weaknesses of the present ESRD reimbursement system, the merits and problems of the proposed changes to the Program, and the impact those proposed changes would have on the delivery of ESRD services to which all Medicare beneficiaries are entitled by federal law.

1. Background of the ESRD Program

In 1973 (Public Law 92-603) Congress extended Medicare coverage for transplantation and dialysis by expanding the definition of disabled to include ESRD patients, regardless of age. Section 226A of Title XVIII (Medicare) of the Social Security Act thereby entitles all Social Security enrollees and their dependents to government-financed health care. Prior to 1973, the cost of care for kidney patients was borne by the patient and his or her family, some third-party insurance payors and some state programs, including Medicaid for the indigent. Without Medicare benefits, kidney failure resulted in a medical and financial catastrophe for most patients. In addition, because reimbursement for services was not assured, the resources for providing care in the health delivery system were inadequate. The few hospitals and free-standing facilities that had transplantation and dialysis services were required to allocate those services, and hence, life itself, among patients. Congressional enactment of the ESRD Program in 1973 therefore represented a major improvement in the equity of the Medicare system and immeasurably benefitted thousands of patients.

In 1978 (Public Law 95-292) Congress amended certain portions of the Social Security Act to encourage greater use of home dialysis by paying for certain costs associated with home dialysis theretofore borne by the patient, and by eliminating the 3-month eligibility or "waiting" period for new ESRD patients who began a self-care regimen. These changes properly recognized that institutional dialysis was not necessary for all patients and that the government in its reimbursement policy should maintain a neutrality with respect to the therapy elected by the patient and his or her physician.

In addition, the 1978 amendments directed HHS to establish a reasonable reimbursement policy which encouraged efficiency and economy in the delivery of dialysis services. Thereby, Congress expressed its concern that the cost-reimbursement system associated with hospital-based providers could be improved without jeopardizing the quality or distribution of services to beneficiaries. Unfortunately, HHS never implemented regulations to achieve this statutory mandate.

The most recent Congressional involvement came in the Omnibus Budget Reconciliation Act of 1981 (Public Law 97-35) which focused on potential reimbursement changes which might reduce Program costs through the establishment of a composite rate structure, whereby a single rate would be paid to the provider for both in-center and home dialysis. Since it was assumed that home dialysis costs were less than in-center costs, such a policy would provide an incentive for providers to send patients home for care. The implementation of these 1981 statutory changes through certain regulations proposed by HHS on February 12, 1982 (47 Federal Register 6556 ff) is discussed below.

Finally, a review of Congressional policy concerning the ESRD Program would be incomplete without noting that the delivery of transplantation and dialysis services was also influenced by other federal statutes and implementing regulations affecting the U.S. health care system in general. Most important in this regard was the National Health Planning and Resource Development Act of 1973 (Public Law 93-642) and its various amendments. The purpose of these statutes and similar conforming state laws was to insure that health care services were fairly and reasonably distributed throughout the nation and to counteract the costly duplication of services that had often occurred. Under these laws a dialysis service could not be established by a provider unless it had received a certificate of need from the state health planning authority after review and advice from local health planning agencies. Thus, virtually every renal care facility and dialysis machine in the United States has been deemed "needed" in the area it serves. In addition, this need was in every case confirmed by HHS under the ESRD Program after advice from the regional ESRD Networks established by federal law. The growth in facilities and the number of machines has not been uncontrolled but has merely kept pace with increasing patient need as determined by independent, federally-financed planning agencies. In many situations several providers would compete for the same need designation and the health planning agencies played a constructive role in determining which of these competing providers would best meet the health needs of the local community.

For the past eight years the ESRD Program has been successful, and the Congressional goal of providing care to ESRD patients regardless of ability to pay and other social and demographic factors has been attained. The so-called "death committees" no longer exist. The patient population has grown from 11,000 in 1974 to 60,000 in FY 1982. With greater resources and patient populations to be served, the medical community has also refined and improved treatment therapies, reduced hospitalization, shortened dialysis times, made care more accessible to patients, improved survival rates for transplants, improved dialyzer technology, and assisted many patients in re-establishing productive lives. In the broad array of social welfare programs nurtured by the federal government, few programs can match the unqualified medical and social success of the ESRD Program.

Comparisons with the experience in other advanced countries are heartening. In 1978 the prevalence of dialysis in the United States was 209 patients per million of population. The comparable rate in France was 133 per million; in West Germany, 117 per million and in the United Kingdom, 53 per million. Contrary to the unsupported theories of some commentators, this high prevalence of dialysis in the United States is attributable to the demographic composition of the populations and to European health care policies that deny access to care to sicker and older dialysis patients. (See Prottas, et al., "Gross National Differences in Dialysis Rates", Brandeis University Health Policy Consortium, November, 1981). According to the cited study, 50% of the difference in prevalence rates can be attributed to the racial compositon of the populations. Black patients in the United States comprise between 27 and 35 percent of the U.S. dialysis population. The remaining difference in the prevalence rate can be accounted for by the laudable public policy expressed in PL 92-603 which assures all Americans of care regardless of age or other illnesses. Such is not the case in the United Kingdom, for example, which still rations dialysis to the young and healthy. Only 20% of British centers treat patients over 65 and only 10% of British centers accept all diabetics. As the authors of the cited study conclude:

> "One could argue that it is compassion, not profit making, that is the cause of the extra care provided in the United States. The ESRD program was established largely because we were unwilling to tolerate the tragic choices required to distribute scarce dialysis resources."

No one argues that the American approach to provide access to care for all patients regardless of race, age, ability to pay or degree of illness is wrong or should be changed. Certainly, given the needs of other equally desirable social welfare programs, it is essential that this "open access" policy be implemented in an economical manner. It is this second goal of efficiency which has drawn the most criticism and concern and is the subject of most of the rest of this statement. Nonetheless, we believe that in analyzing the present reimbursement system and the various proposals for altering it, we must never ignore the impact such reimbursement changes could have on the enviable goal of providing kidney services for all ESRD beneficiaries.

National Medical Care, Inc. is a publicly-held, proprietary corporation which provides health care services and products in several countries. NMC began providing dialysis services in 1969, several years before Public Law 92-603. It has grown to provide dialysis services at 160 centers in the United States and Puerto Rico with over 10,000 patients. Each of these centers was established after a need was determined by public health planners to exist. The centers are maintained as free-standing or independent renal dialysis facilities and are reimbursed under Part B of Medicare on a "reasonable charge" basis. Based on an average reimbursement rate of $138 per treatment, compared to a current average reimbursement rate of more than $174 for hospital-based dialysis centers, NMC roughly saves Medicare over $36 per treatment or approximately $53 million per year.' In addition, NMC finances the construction and expansion of its centers through the private capital markets without requiring government loan subsidies or guarantees. Moreover, nearly 50 cents of every dollar earned by NMC is turned back to the states and federal government in the form of income taxes. Most importantly, NMC's quality of care is exemplary. In the past eight years under the ESRD Program NMC has contributed to the Congressional goal of open access of care for all Americans, while at the same time in an era of tremendous inflation, has maintained a constant price for its dialysis service.

2. Review of the Present Reimbursement System

Under the present ESRD reimbursement system which has remained virtually unchanged since 1973, Medicare pays 80% of the reasonable cost (hospital-based facilities) or 80% of the reasonable charge (independent facilities) up to a screen or limit in each case of $138. The remaining 20% is recovered, where possible, from co-insurors or from the patient. One would therefore expect the average annual cost per patient to equal $16,450 (80% x $138 x 149 Rxs). In fact, the cost in recent years has been greater, because facilities are permitted reimbursement in excess of $138 per treatment, if they can document higher costs due to hardship through the so-called "exceptions" process. Over half of the hospital-based facilities have sought and received exception rate status, so that the present average reimbursment to hospital-based facilities is more than $174 per treatment.

Through the exception process the system has evolved into a target rate system for independents and a cost-reimbursed system for hospital-based facilities, despite the fact that there is no evidence to justify higher costs in hospitals. We believe that the failure of HHS to pay a single, competitive and fair rate to all providers for the same service to be the major problem with the existing ESRD reimbursement system. A single rate which fairly covers the cost of, say, 75% of all providers and permits the more efficient provider to retain the difference between its costs and the screen, would decrease programmatic expenses and encourage all facilities (not just the independents) to become more efficient.

The manner in which HHS pays for home dialysis is also wasteful and inconsistent. Eighty percent of the costs of supplies and equipment may be paid directly to patients or their supplier - assignees. Alternatively, a facility may decide to furnish the home patient with his or her supplies, equipment and back-up services, and in such case Medicare pays 80% of costs. Under a third approach authorized by Public Law 95-292, a facility is paid 70% (75% under Public Law 97-35) of its regular in-center dialysis rate for each home treatment for which the facility provides all necessary equipment, supplies and support services. Because of this varied system HHS does not know the actual average cost of home dialysis, although HHS consistently maintains that home dialysis is significantly less than in-center care. Yet, it should be noted that only a handful of facilities have elected to participate in the comprehensive home support program, because clearly the costs of home care exceed 70% of the in-center rate. If home care truly costs $97 per treatment as asserted by HHS in its February 12, 1982 Notice of Proposed Rulemaking ("NPRM"), then one would expect far more facilities to elect the 70% - comprehensive home care alternative. Recent HHS studies indicate that annual home costs are over $17,000 per patient, or $114 per treatment.

Aside from the multiple exception rate problem and the unstructured system of home dialysis reimbursement, a major problem with the present ESRD Program is that it has no way to recognize general inflationary pressures and to translate those into the reimbursement rate in order to provide the necessary incentives for the private sector. As stated above, the $138 screen has been constant for nearly 9 years. Measured in constant 1973 dollars, then, the reimbursement rate has dropped considerably, making it more difficult for proprietary facilities to stay in the market and making it more necessary for hospital facilities to seek higher exception rates. We have reached a point where even the most efficient providers such as NMC are losing money at selected locations.

Despite these problems with the present system and the need for some sort of reform, we can state positively that during the period, 1973 to 1979 the system did operate to provide for expansion to permit access for all U.S. dialysis patients, while maintaining a relatively constant per patient cost. Program costs per patient increased by approximately 2% per year in an era of double digit inflation in the economy in general and in the health care industry in particular. Without denying the need to try to do better for the American taxpayer, it is nonetheless fair to argue that few federal social welfare or military programs had as enviable a record of cost control during the same 1973-79 period.

3. Review of the Notice of Proposed Rulemaking

In general, NMC congratulates HHS for attempting to address reimbursement issues for the entire ESRD Program in the February 12, 1982 NPRM rather than in a series of parts. We agree that the various parts of the ESRD program (hospital-based facility care, independent facility care, home care, CAPD, self-care training and physician reimbursement) should be woven together into a comprehensive, reasonable system. In the past, effects of adjustments in one part of the program on the rest of the system have not been considered. Unlike prior attempts, this NPRM clarifies the system in a useful manner.

In theory, we have no quarrel with the logic of the rate-setting methodology. We believe a prospective system of setting target rates which permits the efficient providers to retain the difference between their costs and the target rate does foster much needed competition in the health care industry. Further, we agree that relating the target rates to accurate and timely cost data from a fair sampling of facilities is reasonable. As discussed below, however, we strongly believe that the legitimacy and effectiveness of such a prospective rate-setting methodology can be subverted by using stale, homogenized, and unrealistic cost data. We also believe that the composite rate technique of melding home dialysis and in-center dialysis costs into a single rate is worth trying, although we believe that the expected conversion of center patients to home care is unlikely. We feel that HCFA should try this approach (with a healthy attitude toward modifications if it turns out badly) provided, again, that realistic data, which include a fair labor factor, are used. In other words, we believe that the basic system is appropriately designed but that the data input is incorrect.

We specifically agree that in setting rates for the same dialysis service, hospital-based and independent facilities should be treated identically. We agree that there are no data that support or justify higher supply or labor costs for hospital-based facilities. Suggestions that patients treated at in-hospital centers experience a higher rate of hospitalization than patients treated at independent facilities, even if true, do not support the conclusion that hospital patients are sicker or require a higher degree of care. First, hospital facilities care for the vast majority of CAPD patients who experience higher hospitalization rates due to inadequate dialysis and other complications. Second, due to physician habit and convenience and hosptial admission pressure, patients at hospital-based centers are more likely to be admitted as inpatients than patients with the same problems or complications who are being treated at free-standing, independent facilities. Third, hospital-based centers also very often provide acute or in-patient dialysis within the outpatient facility, and, unless the sample of patients is carefully screened to eliminate these inpatients and transplant patients, the resulting hospitalization statistics are meaningless. Comparisons of age, race, and diagnostics demonstrate that there is no meaningful difference between patients treated at hospital-based vs. independent facilities. Note that there is evidence that hospitals in some states, such as Texas, rarely if ever seek rates above the present $138 screen, whereas hospitals in other states, such as California, consistently seek and receive higher rates via exceptions.

HHS has taken the correct approach in interpreting Section 2145 of P.L. 97-35 as requiring a dual rate system only if, and to the extent that, such separate rates were justifiable and were, in the Secretary's opinion, economical. In fact, the statute can be interpretated as preferring, or indeed requiring, a single rate and permitting a departure from a unitary rate only upon findings that a dual rate would be more economical.

Tied to our belief that a single rate for the same service promotes economy, is our belief that the most destructive element in controlling payments under the present system is the proliferation of exceptions above the $138 screen for hospital-based providers. Therefore, we agree wholly-heartedly with the proposed regulations insofar as:

> "These procedures and criteria are designed to discontinue the practice followed in the past with respect to granting exceptions. Instead, we expect that under the proposal few facilities would be able to qualify for exceptions to their payments rates."

To be sure the exception process does not become a large loop-hole the reimbursement rates themselves must be set at a realistic level. The projected $132/128 level is wholly unrealistic for the reasons stated below, and there will be a stampede to the exceptions window by hospital-based and independent facilities alike. The proposed regulations could easily be interpreted by a court to permit many exceptions where the reimbursement rates are intentionally set below the cost of 46% to 60% of the hospital-based and 28% to 40% of the independent facilities. A very large percentage of facilities could show that their cost exceed the reimbursement and that they are "isolated essential facilities" under proposed reg. section 405.439(g)(2). The argument can be made in one of two alternative ways: A facility could show that by virtue of the health planning process it is "isolated and essential". The findings of the SHPDA in any CoN process basically state that the facility provides nonduplicative services. This could be equally true in dense urban areas as well as rural areas. Alternatively, all the facilities in a given area could jointly apply for an exception and convincingly state that they collectively represent all the dialysis resources in any given area and that they are all underreimbursed by Medicare. We believe that, where the rate is set so low as in these proposed regulations, a court could easily gloss an expansive reading onto the exception provisions.

The exception process itself, whether under the present system or the proposed system, discriminates against proprietary, independent facilities in so far as Medicare "allowable" costs exclude certain real costs experienced by these facilities, such as bad debts, related organization mark-ups, return on equity, shareholder maintenance costs, etc. (see discussion below). Since these expenses cannot be recouped under the exception process, the only alternative available to independents, even if they are able to meet other "hardship" criteria, is to close. As a result, the exception procedure encourages the expansion of inefficient, hospital-based facilities in areas of unusual hardship by eliminating the competitive dynamic which the independents bring to the system, with obvious higher cost to the Medicare program. It is this discrimination in the exclusion of nonallowable expenses under the exception process which explains why isolated areas such as Wyoming and South Dakota are serviced only by high cost hospitals.

The solution is two fold: first, set the rates at a realistic level which does not underreimburse all facilities and which provides an incentive for low-cost providers to expand and replace high-cost providers; and secondly, eliminate the exception process completely, or at least eliminate the g(2) "isolated essential facility" criterion.

We also agree with the NPRM approach toward periodic review, but we believe that such review should be required annually and that the intermediaries and HCFA be required to publish generally, or notify the facilities specifically, of the basis for the reviews, even where (or especially where) the review results in no change in the reimbursement rate. Annual reviews are essential to conform to the law which now requires a prospective rate-setting methodology.

The NPRM does not specify how these periodic reviews will be conducted or how subsequent cost data will affect the reimbursement rates. A methodology that periodically lowers the median through the elimination of higher cost providers would result in a "rachet effect", which will eliminate 50% of all providers after each periodic review, until the median becomes the minimum. Such a technique would obviously cause extreme undercapacity, proliferation of exception rates and elimination of any incentive for low-cost providers, and is strongly opposed by the undersigned. The final regulations should disavow this methodology, lest the fear of such a ratchet effect result in a cessation of investment and expansion in the industry by the low-cost providers. Even low-cost providers will abandon the industry if the long-range plans of HHS are to squeeze the margins and eliminate any incentive from the program. The obvious result will be a return to the inefficient, cost-reimbursed system. Instead, these periodic reviews should focus on inflation (or geniune efficiencies, if these occur) and adjust the medians and composite rates accordingly, while maintaining the initial medians as a floor in order to provide necessary incentives.

As previously indicated, unless the data HHS uses in its methodology are adequate and timely, the resulting reimbursement rates will not produce the intended results. Although it is improbable that HHS could satisfy all providers with its selected data base, the data base used by HHS in the NPRM is universally deemed both stale and unfairly inadequate.

With respect to independent facilities, HHS admits that 15% of reported costs were eliminated, thus reducing the total base cost from $126.66 to $107.66. The raw data do not clearly indicate what categories of expenses were excluded, but we do know that three major items were eliminated. First, the cost data exclude normal bad debt write-offs. Under Part A reimbursement principles such eliminations make sense, because the bad debts are restored dollar-for-dollar by Medicare retrospectively. In this sense, bad debt is thus a separately reimbursed item. However, under the present and proposed ESRD reimbursement system, uncollectible receivables i.e., "bad debts", are indeed real costs of doing business. There is no way that the Securities and Exchange Commission would permit a company such as NMC to report earnings which did not reflect this cost item. The restoration of bad debts up to "allowable" cost, which is proposed in the NPRM, is another example of a policy that discriminates against independent providers whose costs, based on HHS audits, include 15% "non-allowable" expense items. Thus, the proposed restoration of bad debts reflects an extension of cost-reimbursement attitudes that nurture the inefficient, high cost providers and stifle competition by treating the low cost providers differently. Instead, an evenhanded policy of full restoration of documented bad debts for all participants would implement the Congressional preference for competition and efficiency. There is no statutory or logical basis for excluding bad debts.

Similarly, there is no legal authority for excluding a fair return on equity from the cost basis. Even Part A reimbursement principles allow such a return on equity. If all other expenses were covered by the $128 rate, an independent facility would still not participate in the program if it could not recover some return on its capital investment commensurate with the opportunity cost of not investing that capital in other endeavors. Moreover, the exclusion of such a return from the cost basis is illogical when one considers that interest on debt financing would be included as an appropriate expense. Thus, a $1 million facility could legitimately increase its allowable costs by, say, $150,000 per year by borrowing the capital from a commercial lender. This exclusion, then, does not fulfill the Congressional mandate to devise an economical system, and in fact violates both the Social Security Act and existing HHS regulations.

Thirdly, the HHS cost data for independents exclude so-called "excessive" compensation for managers, many of whom are also proprietors or partners in owning the facility. There is no justification for these exclusions. It could well be that an otherwise efficient low-cost provider does pay larger than normal salaries to its chief executive. Why should HHS care about the range of expenses in any particular category, when the "bottom-line" is within the screen? HHS is here mixing a statistical method of setting a screen by fixing the rate at the median of all costs with a modular method of comparing individual expense items with the "normal" amounts for such items. This is not only unreasonable, but such an approach infuses an inflexibility into the system which discourages providers from trying new approaches to reduce total costs. It may well be that only by paying an "excessive" salary can a facility attract top-quality managers who are able by virtue of greater managerial skill and effort to reduce overall costs. We believe this homogenization of cost data by HHS to be unnecessary and potentially counterproductive as well as inconsistent with Congressional intent. Another similar example is the exclusion by HHS of costs of providing office space at the facility for physicians who function as administrators and managers. Also excluded from the cost base are expenses borne by proprietary facilities which are associated with disclosure and reporting to shareholders, the government and the public in general. The preparation and dissemination of business and financial information by publicly-held corporations is legally required and enforced by the Securities and Exchange Commission. Facilities which choose to raise capital from public investors (to the benefit of the government) cannot avoid these expenses and are just as reasonable and necessary as personnel or supply costs.

The exclusion of all these expenses artificially and unreasonably deflates the cost of providing the dialysis services by 15%.

However, basing the prospective reimbursement rate on an artificially deflated cost estimate will not save ESRD Program dollars. Instead, it will lead to increased use of the exception process and higher ultimate Program costs.

The audited costs are suspect because no facility was given the opportunity to appeal costs which were excluded by HHS. If an auditor made a clerical or judgmental error there was no mechanism of discovering or correcting the same. Moreover, the cost audits were performed by various agents throughout the country, and from even a cursory view it is obvious that the audits were inconsistent in methodology.

Aside from the data's inadequacies, they are clearly five years old. Based on health care industry experience an inflation factor could, conservatively, be set at 50-60%. HHS believes that the non-labor component (roughly 59% of independents' cost and 65% of hospitals' cost) has not been affected by inflation. Although we disagree with this assertion, applying a 50% inflation factor to labor costs alone would raise the target rates by 21% for independents ($155) and 19% for hospitals ($158). Our own experience underscores the need for such inflation factors. We are widely recognized as the most efficient provider of dialysis services and have worked hard to maintain productivity in a time of unprecedented inflation without any increase in the $138 screen. Between 1978 and 1981, while maintaining a constant 3 to 1 ratio of patients to direct patient care staff during dialysis, we were able to increase our overall patient/staff ratio from 4.6 to 1 to 5.7 to 1, but our total facility labor costs per treatment increased by 46%, or roughly 15% per year. In other words, despite our best attempt to fight inflation by improving staffing ratios by 24%, we still experienced a large increase in labor costs. We sincerely believe that our experience is better than other providers in the industry.

We believe the Department should consult with all segments of the industry, both hospital and independents, on the question of Program costs. It is crucial to derive a more realistic cost estimate, because if the prospective rate is set too low, wasteful exceptions, not economy, will result.

The NPRM reflects the strongly held belief by HHS that home dialysis is significantly less expensive than in-center dialysis, yet the HHS data clearly contradict this belief. As previously mentioned, the $97 median cost of home dialysis is suspect, because the sample included only 5% of all homedialysis programs and the sample was heavily weighted in favor of the largest and most efficient programs. Moreover, the cost evaluation did not include universally recognized auxilary costs associated with home dialysis, namely: (1) the cost of hospitalization associated with higher morbidity among CAPD patients; (2) certain capital and operating costs such as plumbing and electrical construction costs and additional utility expenses which are not included in the cost of the home dialysis sponsor; and (3) the opportunity cost of labor furnished by a family member who assists the patient on dialysis. Moreover, it is not clear from the NPRM whether the cost of the equipment is included in the $97 figure. It also is important to note that the 17% of the dialysis population currently using home dialysis is a very select group of patients. As the home patient population expands, sicker, older and poorer patients will be added to this population, and the median cost can be expected to increase substantially. A more comprehensive study conducted by the GAO which tracked the cost of home care for 308 patients concluded that the median cost of such care was $105.34 per treatment (exlcusive of home aide cost), again based on the present selective sample of healthier patients. Recent HHS studies show a home cost of $114 per treatment.

The labor component of approximately $12 represents the cost of personnel at the center who are used to service the home patient. It does not include the opportunity cost of the free labor of a family member or the cost of a paid assistant. At a minimum, the per treatment cost of a paid assistant would add another $25-30 onto the cost, thereby eliminating any supposed cost savings over efficient in-center care. Thus, it is only by forcing the patients' spouses, children and friends to donate 15 to 20 hours per week (the equivalent of a half-time job) that HHS can expect to save $100 million or so per year. The NPRM is saying, in effect, that if providers and physicians wish to cover their costs and stay in operation, they can do so only by using the free labor of the patients' family members. Surely, this is not the intent of the statute.

Recent studies have clearly demonstrated that the U.S. dialysis population is more diverse, poorer, sicker and older that the dialysis population of any other western industralized country. For example, the current median age of the U.S. in-center dialysis population is 56 years compared to 49 years for home patients. While 34% of in-center patients are non-white, only 15% of home patients are persons of color. In addition, 32% of in-center patients have medical complications of diabetes or hypertension, but only 17% of home patients suffer from these complications.

Based on these studies, it is not at all surprising that 83% of these patients are in-center. The view that physicians and providers are "keeping" the patients in-center is cynical and wrong and the attitude that patients don't know what is "best" for themselves and their families is patronizing and wrong. Home care simply does not present an acceptable alternative for over 40% of the U.S. dialysis population, as the NPRM supposes.

The home care reimbursement proposal poses a special burden on many independent facilities, because the patients referred to these facilities from the hospitals have already been screened for home care. Thus, the hospitals have trained and will continue to train, the most suitable patients for home care. In many cases independent facilities have no home patients because they are only a part of an integrated referral system in which the hospitals perform home training and home back-up and the independent facility never treats patients who are able to go home. This obviously explains the difference between the percentage of home patients carried by hospitals (23%) and by independents (10%). For any facility to survive under the proposed reimbursement system, its percentage of home patients must be greater than the national average. Obviously, because many independents will not be able to accomplish this goal, they will fold and their in-center patients will return to the hospitals, not for home care, but for hospital in-center care which is concededly at least 26% higher than independent in-center care ($135 vs $108). Consequently, total program costs can be expected to increase over time.

We believe there is no support for the following statements on page 6568 of the NPRM:

> "CAPD is the preferred treatment for may (sic) patients because it causes relatively little disruption in the patient's life ... Because of the potential benefits to many patients and to the Medicare program, we would like to provide facilities and physicians with incentive to service patients who are appropriate candidates for CAPD ..."

In fact, the currently available evidence compels the opposite conclusion: the medical problems and disappointing success rates associated with CAPD require that HHS not encourage facilities and physicians in prescribing this therapy, except for the relatively small group of patients whose medical condition contraindicates routine hemodialysis.

1. The comparative hospitalization rates of CAPD patients indicate inadequate dialysis and significant complications such as peritonitis, resulting in sicker patients and higher costs. Data from the NIH, CAPD Patient Registry (December 15, 1981) show that 48% of CAPD patients are hospitalized within the first three months of initiation of CAPD. By the end of nine months only 16% of these patients were not hospitalized, i.e., 84% were admitted within the first nine months of CAPD. One should note, moreover, that the NIH study tracks CAPD patients from the most experienced programs and if nationwide data were examined, these negative results would be accentuated. HCFA's Medical Information System data for December 1981 reveal that peritoneal dialysis patients (over 18) (who are similar to the general dialysis population in terms of age, sex and disease categories) spend an average of 34.2 days per year in the hospital, compared to 18.7 days for hemodialysis patients. In the 18 to 45 year old age group the comparative stays are 34 days per year (peritoneal) and 17.5 days (hemo). At a conservative cost of $200/day this difference costs Medicare an additional $3,300 per year per patient.

2. The drop-out rate for CAPD is stunning. In the United States, 12 months after initiation of CAPD, 57% had dropped-out due to death and abandonment, i.e., only 43% remained on CAPD after the first 12 months. The reported European experience is similar. As reported in the Lancet (January 23, 1982), drop-out rates for death and abandonment of CAPD were 43% at one year and 68% after two years. Recent Canadian studies also show similar drop-out rates.

3. The CAPD death and abandonment rates are similar to death and abandonment rates for dialysis patients who are inadequately dialyzed as reported from the National Cooperative Dialysis Study. That Study also indicates that the dialysis prescription, resulting in inadequate dialysis, may have "long-term effects which do not change immediately when the dialysis prescription is altered." In other words, if CAPD results in inadequate dialysis as suggested by current data, these complications may not be readily reversible.

The importance of these findings concerning the adequacy, risks, costs and marketing strategies of CAPD therapy for ESRD patients is clear. First, as the cited data on CAPD hospitalization and drop-out become more widely disseminated and reviewed, the medical community is likely to find these risk unacceptable for dialysis patients. Public policy should respect this judgment and should, at the least, remain neutral. In no way should public policy encourage or prescribe a treatment therapy which would not otherwise be acceptable for all but a relatively small group of patients. Moreover, we believe that given the overwhelmingly negative data, HHS and other public insurers would be justified in denying payment for CAPD (except in those cases where hemodialysis or transplantation is not possible), until further, carefully controlled studies are completed and indicate otherwise.

Second, aside from the goal of avoiding prescription by regulation, the evidence concerning CAPD strongly suggest that CAPD is a costlier form of treatment. If the largest and best CAPD programs have a median cost of treatment which is 31% higher than home hemodialysis, it seems preferable to discourage the more expensive form of therapy. Further, the additional hospitalization associated with CAPD raises serious questions concerning the adequacy of CAPD dialysis, and the long-range effects of inadequate dialysis will definitely result in sicker patients whose cost of care will naturally rise.

Third, the skillful marketing of CAPD, which has increased the home dialysis population from 12 to 17 percent in less than three years, prior to the collection, analysis and dissemination of CAPD experience should influence public policy decisions, insofar as including these patients in the composite methodology formula artificially inflates the percentage of home patients and therefore lowers the composite rate. In other words, through the use of a composite rate which assumes a 17% home patient percentage, HHS insures financial loss to facilities which are unable to meet or exceed this rate. As the fervor for CAPD cools, as it inevitably otherwise would based on the cited data, more and more facilities will be underreimbursed. Public policy should not ask facilities to choose between financial ruin and unnecessary risks for their patients through undesirable treatment modalities.

In addition to its effect on the proposed composite rates, the inclusion of CAPD patients in the home patient pool, leads to unreasonably inflated expectations concerning the percentage of the U.S. dialysis population that can be maintained adequately outside a center. If one discounts the growth in home patients resulting from CAPD therapy, we are left with a 12% home percentage with no evidence of an upward trend. Therefore, the HHS prediciton of 30-40% on home dialysis within 5 to 7 years (page 6577, column 3 of NPRM) is unsupportable. If 90% of the home patient growth has come from CAPD which is unacceptably risky, we expect very little growth in home care above the 12 percent figure (unless, of course, HHS is willing to pay for home aides in which event home care is more expensive than efficient in-center care).

Impact of the NPRM and Summary

The conceded, principal goal of Congress and HHS in deriving a reimbursement system for ESRD services is efficiency. Congress has clearly abandoned the cost-reimbursement mode which has been such a failure in the U.S. health care industry in general and favored a pro-competitive, incentive approach, which encourages the most efficient provision of services and eliminates high cost providers. As previously explained, due to the liberal exception process the ESRD system has become a cost-reimbursed system for hospitals and a static, and increasingly inequitable system for independent providers. Any fair judge of the program can readily observe that the high costs have resulted from the inability of HHS to look at costs of the inefficient rather than the profits of the efficient; this has resulted in a four year delay in implementing the 1978 Congressional mandate expressed in Public Law 95-292. To perpetuate a system that readily and uncritically pays a non-taxpaying institution over $250 for maintenance dialysis, while at the same time berates and punishes a taxpaying facility for requesting $117 for the same services is shameful.

As discussed above, the proposed methodology goes a long way in correcting these mistakes. Nonetheless, the use of faulty assumptions and outdated and inadequate data undermines the potential success of a rational methodology, in so far as the impact of reducing the present $174 (approximate)/$138 rates to $132/

$128 will underreimburse approximately half of all dialysis facilities in the United States.

As the operator of 160 dialysis facilities caring for over 10,000 patients nationwide, we believe it is our responsibility to HHS, our patients, employees, affiliated physicians and our stockholders to state clearly that, if these proposed rates are implemented, a large number of our facilities may have to close. We presently have 50 to 60 facilities that would be underreimbursed based on the proposed methodology. This impact was disclosed in a letter to the Secretary dated December 11, 1981. In the past, statements such as these have been viewed by some in the government and the media as threatening or intended to scare patients. On the contrary, we simply believe that these facts should be disclosed prior to the finalization of public policy. Moreover, we would be derelict in our fiduciary and legal responsibility if we did not disseminate these facts to our stockholders and the general public who every day trade in the stock of NMC. Our statements to HHS and the public have been consistent.

Presently, on average the reimbursement rate for dialysis services in the United States is approximately $160 per treatment. None of our facilities receives this rate, and we believe the rate can and should be reduced. Setting a single rate of $150 per treatment, for example, would eliminate high cost providers, encourage efficient providers and save the Taxpayers approximately $90 million per year.

NMC believes that the government should pay no more for critical social services for the poor, disadvantaged and disabled - whether these services are for food, housing, or health care - than is absolutely necessary. Over the past 9 years NMC has saved the government millions of dollars by providing high quality dialysis services at a constant price, while cost-reimbursed providers have continually raised their prices for the same service. To believe that the proposed rate cut would not jeopardize the continuation of these services at many NMC facilities is economically unrealistic. Whatever rates are established, NMC will do its best to continue to provide dialysis services efficiently to the largest number of patients at the greatest number of locations, but we cannot say that many of our facilities would not close. Wherever and whenever an NMC facility faces closure due to these economic factors, we assure you that we will give HHS through its regional offices ample notice and will cooperate fully with HHS and local agencies to provide uninterrupted care for patients whose welfare is our common responsibility.

The ESRD Program is the best example I know to illustrate the proposition that Government can improve the lives of people. The ESRD Program has literally saved thousands of lives - lives that are lost in less compassionate and less resourceful nations. The present attempt by this Congress and Administration to eliminate waste and make the Program more efficient is an endeavor in which National Medical Care will cooperate with all the resources at its disposal.

Respectfully submitted
on behalf of National Medical
Care, Inc.

By Timothy McFeeley
Timothy I. McFeeley

April 19, 1982

TIM/ccc

Chairman **Rangel**. Thank you.

Are you saying free-standing clinics are less expensive and more efficient than home dialysis at hospitals?

Mr. **McFeeley**. Yes, sir.

Chairman **Rangel**. Are you a doctor?

Mr. **McFeeley**. No, sir.

Chairman **Rangel**. How many of the people who have come into your organization's network are in home dialysis?

Mr. **McFeeley**. I do not have statistics for the national. I would say ours mirrors the national rate, which would be roughly 12 percent of hemodialysis patients. I do not have good statistics in terms of the CAPD statistics. It varies greatly from center to center.

Our center in Boston, for instance, has 23 percent of its patients at home. It has a very good, active home program. The choice of therapy is one that is principally decided by the patient and the physician, and these preferences and the available resources and other factors vary from center to center.

Also, one other point I would like to make on that would be, in some instances, particularly in urban area, Mr. Chairman, our centers take patients that have been screened through hospitals. Our patients do not come off the street. They come from hospitals. The hospitals may have the home training program. In other words, the patients come through the hospital. If they are good home candidates, they are trained by the hospital and we do not get those patients.

Chairman **Rangel**. So your percentage could be much lower because they have already been screened and you would be getting those not eligible?

Mr. **McFeeley**. Many of our centers do not have home centers, for that reason.

Chairman **Rangel**. Since the hospitals are sending you so much business, why are you knocking their rate? What difference does it make to you what we reimburse the hospitals as long as what you are getting is an equitable return for your investment?

Mr. **McFeeley**. The reason is, the resources at the disposal of the ESRD program are limited. All resources are limited. I want to see the maximum amount of care for the maximum number of patients in the maximum number of locations.

Chairman **Rangel**. Let me ask you this. Were you here this morning?

Mr. **McFeeley**. Yes, sir.

Chairman **Rangel**. Did you hear the doctor from George Washington?

Mr. **McFeeley**. Yes, I heard Dr. Thompson.

Chairman **Rangel**. Do you have a list of things similar?

Mr. **McFeeley**. No, frankly.

Chairman **Rangel**. Does your firm, does the National Medical Care, Inc., have certain criteria to determine who can receive the benefits of your services?

Mr. **McFeeley**. No, Mr. Chairman. Decisions like that would be generally in the discretion of the medical director. I am frankly very surprised at that particular anecdote.

I could trade anecdotes. I have any number of doctors often call me, medical directors, asking me as corporation counsel, what can we do about obstreperous cases with patients. Some are really quite extreme, and I can tell you our policy as a legal matter.

Chairman **Rangel**. There are cases that even a lawyer could look at and believe the patient should be in a hospital and not in your center, right?

Mr. **McFeeley**. Yes, even a lawyer could do that. [Laughter.]

The law is quite clear, we have to do everything to our utmost power to keep those patients and treat them if that is their preference.

Chairman **Rangel**. I do not want to get too involved in how you run your business. But it seems to me that you have to spend as much time understanding the problems hospitals are having with the type of patients they are getting, not from your firm, but assuming that all of the witnesses are telling the truth—and I do assume that—then we politicians have a problem.

If your rejects will be sent to the hospital because they take too much time and bother, they do not have the option to reject patients that you do, then you have to get together with them and both of you come up with something from which the patient is the beneficiary and from which you do not go broke.

Mr. **McFeeley**. I truly agree that we do not reject patients for those kinds of reasons.

Chairman **Rangel**. You do not, but somebody else does.

Mr. **McFeeley**. Those are anecdotal incidents.

Chairman **Rangel**. No. She gave me a list here that came from the people. This is a note the private sector gave the patient, "Patient Acceptance Guidelines." It was not prepared by the hospital.

Mr. **McFeeley**. No; I understand that.

Chairman **Rangel**. So what I am saying is, do you not believe you people should have a conference and determine within rules of ethics that protect the patients how you will make these adjustments, so that you do not have to come in saying, the hospitals are being overpaid, that you can just come in and take care of what you are providing?

How would I know you are cost effective? Do you provide any information as to what returns you make on the investment? How would we determine, as politians, which modality is more cost effective, as one lawyer to another?

Mr. **McFeeley**. We file cost reports that are required by the Health Care Financing.

Chairman **Rangel**. Does that show the cost of physicians, the cost of equipment, the return on investment?

Mr. **McFeeley**. It shows the costs of providing care at that facility. You also know that we do not charge the Government more than $138. You can also look at our financial statements as a corporation that are filed with the Securities and Exchange Commission and see what we do, although I caution you there we are involved in some other industries, some aspects other than dialysis.

Chairman **Rangel**. Did your firm help to assess your clients as to the serious nature of this proposed regulation and the impact it could have on the availbility of services by your corporation?

Mr. **McFeeley**. Yes. We felt it was important to make sure that people had information available to them, both our doctors and the patients and our staff. The Federal Register is not widely read among these groups and we thought it was important to make sure they knew what proposals were being set forth by the administration.

Chairman RANGEL. So what educational methods did you use for your patients? Did the doctors, when the patient was hooked up, give them a copy of the Federal Register? [Laughter.]

Mr. McFEELEY. I do not know how in every case our patients were informed. What we did was to send a letter and a description of the regulations and copies of it to our various facilities and ask them to inform the doctors of that. And I think the doctors through their own organizations, professional organizations, were also getting that kind of information, and they were passing it along to the patients. And the word would get out that way.

And if patients were interested in getting a copy of the Federal Register, we would furnish a copy.

Chairman RANGEL. How would it help you if the patient was well informed of the regulation?

Mr. McFEELEY. We feel it is important for the patient to know in order to understand what the proposal was here, if in fact there could be some changes brought to bear during the comment period. This was a notice of proposed rulemaking. The administration was seeking comments from the public. And what we were doing was saying to the patients or to the public in general, these are going to affect you, if you would like to comment here is where you write and you only have 60 days to do it.

Chairman RANGEL. Did the Register indicate how many centers may be forced to close as a result of the proposed regulation?

Mr. McFEELEY. In the impact statement they said 46 percent of the hospitals and 28 percent of the independents by their reckoning would be under-reimbursed. That does not mean they would be forced to close, but——

Chairman RANGEL. No, but I met a lot of patients and they seemed to believe they knew exactly where the centers would be closing, and they had a concern because they were being serviced by them.

Mr. McFEELEY [continuing]. No, the Federal Register had nothing to say about that.

Chairman RANGEL. Was that a part of your educational program?

Mr. McFEELEY. Part of our responsibility as well is to our stockholders, aside from what we were telling patients that the Government was doing, was to say, what impact does this have on this particular corporation.

Chairman RANGEL. I am not talking about the stockholders.

Mr. McFEELEY. Our particular corporation would be affected by these regulations.

Chairman RANGEL. You do what you have to do to make a dollar. I am saying that a lot of people came to Washington and some dialyzed themselves on the Capitol steps, and they said they knew their centers back home were being closed. And that was not in the Federal Register.

Mr. McFEELEY. I do not know where they got that information.

Chairman RANGEL. Well, let me try again. The speaker came to me and said a couple were being closed in his district.

Mr. McFeeley. There were several centers we identified———

Chairman Rangel. He is from Boston.

Mr. McFeeley. Yes, sir. He is my Congressman.

Chairman Rangel. You have been most effective in getting the message across to the patients and to the politicians, and perhaps we will send some separate questions to be answered.

Let us hear from the other witnesses.

STATEMENT OF ROBERT L. GREEN, CHAIRMAN OF THE BOARD, COMMUNITY PSYCHIATRIC CENTERS, SAN FRANCISCO, CALIF.

Dr. Green. My name is Robert Green. I am chairman of the board of a company named Community Psychiatric Centers, which, despite its name, has 38 outpatient dialysis centers, independent centers, and as such we are the second largest operator of independent centers in the United States, a far distant second to National Medical Care. And I have very brief comments.

First of all, we believe the audited cost data of $108 per treatment for independents is out of date and understated, and we would like to get better data. That comment has been made by other witnesses.

Second, although the proposal states the rate will be reviewed, there is no commitment on the part of HCFA to review the rate annually, and therefore it appears that the burden and impact of inflation will be on our shoulders. We believe there should be a commitment for annual review. That is, inflation protection.

Approximately half of our facilities—I did not send in a text. I am just using notes. Approximately half of our facilities are in rural areas where we are the sole provider, and as such cannot screen out unstable patients, nor do we do it otherwise. And some of these locations are places like Dothan, Ala., Gadsden, Ala., Phenix City, Ala., Eldorado, Ark., Mountain Home, Ark., Pine Bluff, Ark., Winterhaven Fla., Valdosta, Ga., Medford, Oreg., Orangeburg, S. C., and so forth.

The sole provider exception in the regulations states that exceptions will be granted if the sole provider is losing money, apparently to allow the provider to break even. This does not provide an incentive. A reasonable return should be allowed to sole providers under the exception process in order to provide an appropriate incentive.

The data cited in the proposal regarding home dialysis in our judgment is very weak. The composite rate concept is new. Specifically, we do not believe home dialysis will prove to be less expensive or that there is adequate evidence at this time to rely on new technologies, such as CAPD. Therefore, from our perspective HHS is betting too much on a composite rate.

In response to some of the things that have been brought up this morning, I would like to make some ad libbed comments. First of all, how does the home treatment incentive work? Will the corporation force patients to undergo home treatment to make money? Will hospitals have to drop out of the program because of underreimbursement?

My answer to both of those is no. We would be delighted to lease or subcontract with general hospitals to provide the identical service in the identical space at $138 a treatment and not ask for exceptions. We have tried to do that for years.

As a matter of fact, one way the dual rate got into the budget reconciliation legislation was the fact that we had written letters to general hospitals asking them if we could do exactly that. Hospitals screamed and said that was unfair, and that stimulated the dual rate.

I do not understand why the Government would not want to save money by having the same service provided in a general hospital by an independent provider. Under that circumstance, you would avoid having these weakened, so to speak, institutions, weakened financially, providing the service.

You would have a larger organization. You would avoid the patient mix problem because you would have a lot of patients all over the country in a variety of settings, independent and hospital based. And we would be able to take care of stable and unstable patients for the same price.

Also, you would avoid the small unit problem, a six-bed unit which seems to be financially impractical. Also, we would be required to follow the orders of the doctors. We would not be able to send a patient home because of this or that reason. We would be under the doctor's control.

We have no doctor ownership. We do not participate with the doctors in the profitability of the unit. We would have a healthy dialog between the doctors and the management for quality care, and that is usually the case in an organization such as the hospital, where the administration and the doctors work out the regimens, and the business is run for quality care, but some practicality is involved.

Therefore, if the Government wants to save dollars—that seems to me to be the purpose of the new regulations, to be more efficient and cost effective—I say that national chains are the answer. The corner store cannot compete with a chain supermarket or drugstore, and this is a specialty. It requires specialty services. It requires people who have purchasing power and highly skilled people who can supervise and manage these resources, but follow the doctor's orders.

And I came from San Francisco for this hearing, and I noticed something in the airplane. It is a slight diversion to make a point. I will read an article from a magazine:

> At Brown University's commencement, startled graduates had it socked to them straight from Professor Jacob Neusher's mouth. The learned professor said:
>
> "We the faculty, take no pride in our educational achievements with you. With us you could argue about why your errors were errors, why mediocre work was excellent, why you could take pride in routine and slipshod presentations. For 4 years, we have created an altogether forgiving world in which whatever slight effort you gave was all that was demanded.
>
> "When you did not keep appointments, we made new ones. When your work came in beyond deadlines, we pretended not to care. So go, unlearn the lies we taught you."

He speaks that at a graduation exercise. But what he is really saying is college is not the real world. And I must say that I am concerned, being a dialysis provider, the proposed reimbursement for independent dialysis units may not be the real world either.

National Medical Care has invented, so to speak, the independent unit which provides services more economically.

Quality of care is not an issue. The quality of care is as good in the independent centers as the hospital. There is no evidence that quality is weak in the independent centers. Much to the contrary.

Nevertheless, the proposal does not give incentives to the independents. It kind of slaps them in the face and it says, we will pay you less and we will handicap the hospitals and give them more, even though they have asked for all of the exceptions.

I think it would be better to do nothing at all, to continue to pay $138 a treatment and tighten up on the exception process.

[The prepared statement follows:]

STATEMENT OF ROBERT L. GREEN, CHAIRMAN OF THE BOARD, COMMUNITY PSYCHIATRIC CENTERS

Mr. Chairman and members of the subcommittee, my name is Robert L. Green. I am Chairman of the Board of Community Psychiatric Centers (CPC). I appreciate the opportunity to appear today to explain the position of our company regarding the new reimbursement methods for outpatient renal dialysis services proposed by the Health Care Financing Administration (HCFA).

INTRODUCTION

Notwithstanding the company name, Community Psychiatric Centers is the second largest provider of outpatient dialysis services in the United States. Our company's provision of dialysis services represents approximately 15 percent of our net earnings, and the balance is accounted for by the operation of acute psychiatric hospitals. Although we have a relatively limited stake in the rulemaking proceeding, we are concerned that the proposed rates are unreasonably low—so low as to jeopardize the financial viability of our renal dialysis operations, particularly in rural areas.

In our view, the history of Medicare reimbursement for outpatient dialysis since 1973 has provided a useful lesson. During the past 8 years, one group of providers—the hospital-based facilities—was paid on a cost reimbursement basis, and costs went up. On the other hand, the costs for the independent facilities, which were paid a fixed rate, went down. HCFA has logically decided to apply a fixed rate prospective methodology to both hospitals and independent facilities. The proposed methods for reimbursement of dialysis services do, however, require certain refinements. Our specific comments on the HCFA proposal follow.

LEVEL OF RATES

CPC believes that a fixed rate payment methodology is the appropriate and preferable method for setting payments for outpatient maintenance dialysis treatments. This type of payment system creates incentives for facilities to become more efficient and to be rewarded for that efficiency. However, fixed rates must assure a minimum return to providers of services in order to maintain a climate where capital investment in the dialysis industry will be attractive.

Under the proposed regulations, the current reimbursement screen of $138, which has been in effect since 1973, would be lowered by an average of $10 per treatment. For CPC, however, the reduction would average $15 per treatment (average before payment of $123 per treatment) since a majority of CPC facilities are located in areas where wages are lower than the majority of other dialysis facilities nationwide. Significantly, for the fiscal year ending November 30, 1981, CPC provided 182,287 chronic and acute dialysis treatments at an average cost, before taxes, of $122.76 per treatment.

CPC firmly believes that the proposed rates cannot be justified on the basis of the assertion that the average cost for the provision of dialysis services by independent facilities is $108 per treatment. First, this figure represents only the direct costs of providing dialysis services and does not recognize a return on investment or corporate income taxes. Secondly, this figure was derived from audits of cost reports for 1977, 1978, and 1979. Thus, the computation, in addition to understating the costs necessary for the efficient delivery of dialysis services, is out of date.

In establishing final rates, and in order to implement an effective incentive payment system, we believe that the rates must explicitly provide for some reasonable return above cost for efficient providers. This means including some return on investment in the base rate.

The experience of CPC in providing dialysis services can provide a useful tool. CPC has a reputation for efficient management of resources. Labor costs per treatment are probably as low or lower than those of any other major chain operators in the dialysis field. However, given the proposed reductions in dialysis rates, CPC may not realize a sufficient return on investment to maintain existing capital in this industry and could certainly not attract any new capital. Since the government apparently wishes to continue private sector delivery of dialysis services, it must, in setting payment rates, give consideration to the competitive factors affecting the investment of capital in the health care industry.

INFLATION PROTECTION

As set forth above, the data relied upon to set the proposed rates are outdated and understated. The rates would represent an average nationwide reduction of $10 per treatment and a $15 per treatment reduction for CPC. A 10 percent reduction in reimbursement rates that have been in effect, without increase, for eight years seems especially stringent following a period of steady inflation in labor and medical services generally.

We understand that HCFA intends to review any final rates within one year after publication. However, HCFA has not committed itself to any publication of or opportunity for comment on its findings as a result of this review. We believe that making the new rates effective for a period in excess of one year should require some formal action on the part of HCFA particularly in light of the admitted deficiencies in the data relied upon to set the proposed rates.[1]

In view of the deficiencies in the data, HCFA should commit to republication of new rates within one year after the effective date of these rates based on more current data.[2] However, in the event that HCFA is unable to do so, the regulations should provide for an adjustment to the base rate on an annual basis using a "market basket" index of economic indicators. Dialysis providers should not be saddled with the impact of inflation that could result from any delays in the development of revisions to the final rates.

SOLE COMMUNITY PROVIDER EXCEPTIONS

The proposed regulations provide for an exceptions process that would permit reimbursement above the established rates for sole community providers. About half of CPC's facilities are located in rural areas, and many are the only providers of dialysis service in their communities.[3]

Under the proposed regulations, an exception will only be granted if the facility is losing money under its established rate. Further, additional reimbursement will only be provided to the extent that the revised rate would provide for reimbursement equal to cost. As with all of its facilities, CPC must have a financial incentive to operate its facilities in remote locations. HCFA cannot reasonably expect a proprietary sole community provider to operate indefinitely at cost. Thus, we submit that the exceptions process must provide for a reasonable return on investment for proprietary facilities that otherwise meet any of the criteria for an exception.

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[1] Historically, development of policy in the dialysis reimbursement area has been a protracted effort. For example, Congress enacted legislation in 1978 which directed the Department of Health and Human Services (HHS) to develop incentive reimbursement methods for dialysis services. (Public Law 95-292, § 2.) However, HHS never implemented this provision in the 3½ years between its enactment and subsequent amendment by the Omnibus Budget Reconciliation Act of 1981. The statute had, in fact, directed the Secretary of HHS to promulgate implementing regulations by July 1, 1978.

[2] Annual republication procedures are currently followed with respect to the routine cost limits for hospitals, skilled nursing facilities, and home health agencies under the Medicare program.

[3] The following are CPC facilities that would probably qualify for sole community provider status: Dothan, Ala.; Gadsten, Ala.; Phenix City, Ala.; Sheffield, Ala.; El Dorado, Ark.; Mountain Home, Ark.; Pine Bluff, Ark.; Winter Haven, Fla.; Brunswick, Ga.; Rome, Ga.; Valdosta, Ga.; Jackson, Mich.; Medford, Oreg.; Bradford, Pa.; DuBois, Pa.; and Orangeburg, S.C.

BAD DEBT

Under the proposed regulations, HCFA would make a year-end lump sum payment to facilities for the cost of bad debt. However, this payment would be limited to the amount by which a facility's costs exceeded reimbursement during the year. For CPC, Medicare bad debt in 1981 amounted to $2.58 per treatment.

The limitation on recognition of bad debt would deprive an otherwise efficient facility of any opportunity to make a profit if rates are lower than cost and the amount of bad debt exceeds the difference. HCFA cannot reasonably operate an incentive payment program where payment is artificially reduced to cost. HCFA has cited no reason to penalize efficient facilities with this limitation if the provider has made the requisite collection efforts. Since Medicare bad debt is a recognized cost of providing services under the Medicare program HCFA must remove the "cost" limitation on the year-end lump sum payment.

DIFFERENTIAL BETWEEN HOSPITAL AND INDEPENDENT RATES

Mr. Chairman, there is one final point of great concern to us. Under the HCFA proposal, hospitals would be reimbursed at rates that are, on average, $4 higher than for independent facilities for the identical services. We believe that under no circumstances should the proposed $4 differential premium paid to hospitals be increased. Actually, we believe that a uniform rate would have led to more efficient delivery of services. Competition spawned the independents as dialysis providers. Logic would dictate that the government, which desires to maximize its Medicare dollars, would not pay a premium for services provided in a less efficient treatment modality. We can accept the $4 differential because we believe that our efficiency is such that we can continue to be competitive. Any greater differential would, in our view, be unjustified and anticompetitive.

CONCLUSION

In summary, Mr. Chairman, HCFA is currently faced with its first opportunity to implement a fully prospective incentive payment system under the Medicare program, and we would like to see this effort succeed.[1] However, we are enormously concerned over the impact of the proposed rates on our ability to continue to provide dialysis services. We do not intent to close facilities if the proposed rates are ultimately adopted. This service is a lifesaving procedure, and we take our responsibilities seriously. However, unless the modest changes I have suggested are made, we would gradually withdraw from the dialysis business, turning the operation of our facilities over to those who could continue to provide the services. However, at this point, no one knows whether there would be any such organizations. We submit that the short-term costs of maintaining a stable delivery system are small compared to the economic and social costs that would result from any significant withdrawal of capital from the independent dialysis industry. Obviously, our industry and this Congress have no interest in seeing the disruptions in patient care that would result from any substantial reduction in the availability of dialysis services.

Mr. Chairman, this concludes my statement. I will be pleased to respond to questions.

Chairman RANGEL. Mr. Green, you are described here as the chairman of the board, Community Psychiatric Center in San Francisco.

What does that have to do with dialysis?

Mr. GREEN. Well, we have two lines of business, and the title of the company is misleading. About 30 percent of our revenues come from dialysis and 70 percent from the operation of acute psychiatric hospitals. They are entirely separate businesses.

Chairman RANGEL. Are you a psychiatrist?

Mr. GREEN. No; I am a businessman.

Chairman RANGEL. What relationship do you have with the doctors? I know you are chairman of the board, but do you talk with the doctors at all?

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[1] The regulations governing reimbursement for independent rural health clinics contain some incentive features. 42 C.F.R. § 405.2425 et seq.

Mr. Green. Periodically. The doctors are independent practitioners, independent contractors. We have a medical director at each unit which we are required to have, but each patient has a doctor of record who may be the medical director or another doctor in the community. We are trying to provide the facility and the nurses and the other support services so the patients can obtain treatment in a convenient place.

Chairman Rangel. Does your outfit have criteria as to which patients you accept and which ones you reject?

Mr. Green. No, we do not, and I alluded to that in our remarks. We are the sole provider in about 20 of the 38 places. We cannot reject patients. Nor do we do it otherwise.

Now, this isolated instance is being exaggerated, I believe. In other words, that is one case.

Chairman Rangel. It would seem to me that you providers should be able to get together with the hospital people and clear up those exaggerations and those isolated cases and to the best that you can set some criteria where the patient is protected, the hospitals are protected and the private sector is protected.

Mr. Green. Well, look, if the hospital is getting an exception and receiving $175 a treatment and we go to the hospital and we say rent us the space, we will pay you so much per treatment, or a flat fee for the rental of the square footage in the hospital, and we charge the Government $138, we have done that. It is hard to get hospitals to turn over their units to us because they can get exceptions and it does provide some issues with regard to administration.

Chairman Rangel. Why should they turn it over to you? That is a business decision. You are in business. They are in business. Why should they help you in your business?

Mr. Green. But if they are losing money, why should——

Chairman Rangel. That is not your business.

Mr. Green. No; certainly it is not our business, but if the regulations are set up so that the economics of a situation——

Chairman Rangel. So you are competing with the hospital, and so you figure that if we can keep their reimbursements lower, you get more business.

Mr. Green. Exactly, and the Government will save money and get the same quality care.

Chairman Rangel. Well, we do not have the same handle on businesses that we have with hospitals, you know. Businessmen do not have to take all of these oaths as doctors do and hospitals do have a higher standard, you know, professionally.

Mr. Green. No; wait a second, I am talking about the unit being in the hospital, under the——

Chairman Rangel. You see, I am not arguing with you. I do not care where the unit is. I am just saying that your competing with the hospitals does not help our problem. It is better that you work those things out with them. But it is a problem when we have to deal with the organizations and we do not deal with the doctors with these organizations. You can understand that, counsel, you know, that these incentives—I do not know who the incentives are for. I hate to believe they are for the doctor. I can understand your posture——

Mr. Green. I do not know who they are for either.

Chairman **Rangel**. You heard the surgeon say that, you know, you have to penalize the patient because he needs a good transplant. You are saying get him out of the hospital because I need the patient.

Mr. **Green**. Well, I am saying that the incentive should be to reward the organization that is the most efficient if your main interest today is spreading the medicare dollars to cover more patients. It seems to me that is the purpose of the whole thing, and that requires some tough decisions. I do not have to tell you that, but to be benign toward the high-cost providers is not going to save money.

Chairman **Rangel**. Well, they said they did not want the same kind of patients you have, that their patients have different kinds of problems, that most of you, even doctors, would believe that there are patients that should not be treated in——

Mr. **Green**. These are outpatient facilities. We are willing to take all patients that can manage the dialysis treatment in the outpatient setting, whether it is independent, in a shopping center, or whether it is right on the third floor of the local general hospital.

Chairman **Rangel**. You have been in touch with the administration; right? I mean, you have tried to communicate your concerns?

Mr. **Green**. I have tried. I do not know if I have succeeded.

Chairman **Rangel**. All right.

Dr. Blagg.

What is a doctor doing at a hearing like this? [General laughter.]

STATEMENT OF CHRISTOPHER BLAGG, M.D., DIRECTOR, NORTHWEST KIDNEY CENTER, SEATTLE, WASH.

Dr. **Blagg**. I would like to start out, Mr. Rangel, if I may, by correcting Mr. Green, that National Medical Care did not invent the independent center. In fact, the center I come from is the first freestanding center in the world. Dr. Scribner invented it in 1962 to get it out of the high cost hospitals.

Mr. **Green**. I stand corrected.

Dr. **Blagg**. On the other hand, I have to agree with him to some extent, in that our view in Seattle is that there is no reason why, for similar patients, hospitals should be paid more than freestanding units. The alternative, of course, that hospitals have is not to go with Mr. Green, as there is no reason why they could not establish their own nonprofit corporation within the hospital to run their dialysis unit. So there are several options.

I do not particularly want to talk today about the regulations, their calculation, and things like that which I have addressed in my testimony.

I would like particularly to talk about home dialysis, as that is one of the issues of concern with the proposed regulations.

Chairman **Rangel**. Your full statement, Doctor, will be in the record.

If you could also enlighten the committee as it relates to the CAPD concern.

Dr. **Blagg**. I will get to some comments on that right away.

Chairman **Rangel**. A lot of people have been talking about it. I would like a doctor to address this.

Dr. **Blagg**. All right.

First of all, home dialysis. Obviously, one of the problems is why there is so much diversity in this country, from Washington State, which has about 55 percent of its dialysis patients at home, to other States which may have as few as 5 percent of patients at home, with a national average of 15 or 16 percent. Whatever those differences are due to, it seems to be clear that the national average could be higher than it is. Maybe everyone cannot duplicate what we do in Washington, but I do not think it would be unreasonable to expect to get 25 or 30 percent, or even perhaps 40 percent of patients at home eventually. This will take time and will not happen immediately.

One thing that supports our contention that more patients can go home is in the recent report from the Orkand Corp. on the HCFA studies on encouraging home dialysis by paying for home dialysis helpers and paying families to assist with home dialysis. Orkand interviewed the medical directors of, as I remember, approximately 30 facilities that were involved in the study and asked them what percentage of their patients were medically suitable for home dialysis and did not have any medical contraindications. The figure was 61.5 percent. And I will point out that the medical direction was from both proprietary and nonproprietary, and both hospital and nonhospital facilities.

OK, some of that——

Chairman **Rangel**. What about the socioeconomic background and all that?

Dr. **Blagg**. Well, I was going on to say that this is obviously a factor too, but if you say that perhaps another 40 percent of that 60 percent could not go home for psychosocial reasons, you still end up with somewhere about 35 percent of the patients who would be very serious home dialysis candidates. So I do not think that HCFA's numbers are unreasonable as a long-term aim.

Now, as part of what has been going on over the last few months, a number of issues have been raised about home dialysis that I might briefly comment on.

Is it safe to do home dialysis? That has been one thing that patients have been asking. I know of no evidence to show that home dialysis is unsafe in terms of patient survival. Again, in the Orkand study, the medical directors were asked whether they viewed home dialysis as being as good as center dialysis, better or worse? Seventy-five percent of the medical directors said that the care provided with home dialysis was as good as or better than dialysis in a center. So there are physicians who feel that it is safe.

Is home dialysis cost effective? This question comes up again and again. In our own program—and we were one of those who were audited—a home hemodialysis cost $65 without a helper in 1980. If you include the cost of a helper, this comes to about $95. We are one of the programs that is using "target rate" reimbursement. This is reimbursement for each home dialysis at 70 percent of the outpatient dialysis rate. With this we are able to pay for home helpers for approximately a third of our patients, and still are financially satisfactory with that reimbursement. I believe that if home dialysis is done efficiently in the same way that proprietary do outpatient dialysis facilities operate by purchasing supplies competitively it is possible to make home dialysis a very cost-effective program.

The question was raised at the Senate hearing as to whether home dialysis might be discriminatory because of the population of black patients and poor patients. I do not believe this is true either. We have patients of all races on home dialysis. It is the social circumstances of the patient which may affect whether he is able to do home dialysis or not.

As for CAPD, I think this is a very appropriate form of treatment for some patients. In our program, 10 percent of our home dialysis patients are treated home peritoneal dialysis, IPD, and 10 percent are on CAPD. I do believe that CAPD has been oversold over the last 3 years and I also believe that we do not have good data on what CAPD costs and what the cost implications of the high dropout rate are, and so on. We need to get that data, and get good data. But for some patients I think CAPD is undoubtedly worth while.

The physician is the key to home dialysis. What the patient finally decides usually is going to be what the physician encourages him to do. One of the problems is how do you get at this? The issue is not just financial, and is not likely to be solved simply by giving the physician more money to send patients home. That is only one factor. The problem is much more complex as was alluded to this morning.

One problem is that the way reimbursement was developed in 1973 favored in-center dialysis. This resulted in a large, increase in the number of facilities, and a great many nephrologists being trained, many of whom have never been exposed to an effective home dialysis program.

Turning now to the reimbursement rates, very briefly, I think the training dialysis reimbursement in the regulations is completely inadequate. A $20 above the screen level for outpatient dialysis bears no resemblance to the cost of training. The Orkand study showed that a training dialysis costs between two and two and a half times what a regular outpatient dialysis does. In our own program, it costs us $2,000 over the cost of the regular dialyses for the course of home dialysis training.

As was said this morning, we need to keep the 100 percent reimbursement for home dialysis machines in the regulations.

I think it is foolish that home dialysis patients should be allowed to deal directly with commercial suppliers for their supplies. As pointed out by several others, this will increase the cost of home dialysis, the facility will have no control over the quality or quantity of supplies that the patient receives, and I hate to think of suppliers being out there competing directly for the patients.

I also agree that home dialysis aides should be permitted, and that the cost of aides should be included in the cost calculations.

I have concern about the composite rate. It is a very interesting idea and I think it might have worked very well in 1973. I am not sure how well it is going to work in 1982, but I believe that we should try it while monitoring it very closely. The reason I wonder whether it will work is that in order to use it to get more patients home, the reimbursement has to be very closely controlled, and I do not know how HCFA will adjust it at just the right level where it will not do harm to patients. It is important, that the hospitals not be put out of the dialysis business, and HCFA must take a great deal of care about this because the hospitals do provide most of the home dialysis training.

Another major concern that I have is that there are now several hundred facilities that do not have home dialysis training programs or support programs. If the regulations come in right now as written, the implication is that all facilities ought to be able to go out and start home dialysis training. I do not think this can or should happen, and if it does, I think we will see bad home dialysis. Then those who have said that home dialysis is bad for you will have some justification for what they say. I believe that HCFA should look at how they might either encourage regionalization of home dialysis training or how they might develop some revenue sharing method so that facilities that send patients to other facilities for home dialysis training and support can receive some reimbursement allowance for this.

As to physician fees, Dr. Scribner and I have always supported the concept that with the alternate reimbursement method the fee should be the same for the physician whether the patient is dialysing at home or in a center. If we are to have a global fee, that is the way we should go, and it should be related to the medicare index so that physicians do not get into this issue of whether the fee should or should not be raised each year.

The glaring omission in the regulations, I think, is consideration of the patient. There is the comment that some patients will have problems with the composite rate because they will pay more in coinsurance, and that this will be a problem especially for patients already in the program. In our program patients are already complaining at this target rate, we are getting more per dialysis than it costs them to do the dialysis, and this will be worse than the composite rate.

But HCFA should also look at positive incentives for the patient, such as the possibility of paying an attendance allowance. I hate to bring up Great Britain because everybody gets concerned about British dialysis policies, but whatever these policies are, they do pay patients at home approximately 15 pounds, that is about $30 each a week, for home dialysis. This helps to cover the cost of electricity and water, and the trouble the patient and family take to do dialysis. This is a concept that HCFA might well consider.

To sum up, apart from some of the specifics that I have mentioned, what we need is good data, which we do not have, about costs, about medical care, and about everything else in the ESRD program. I think that HCFA should not pursue these regulations immediately, but should reconsider them, deal with the issues raised today and give the opportunity for representative individuals to speak to HCFA and help to get all this put together better. I also believe there should be a specific office of end-stage renal disease in HCFA. Finally, HCFA should consider the issues I have mentioned with regard to rates and patient incentives.

Thank you very much.

[The prepared statement follows:]

STATEMENT OF CHRISTOPHER R. BLAGG, M.D. DIRECTOR, NORTHWEST KIDNEY CENTER, SEATTLE, WASH.

Mr. Chairman and members of the Subcommittee, I am Dr. Christopher R. Blagg, Director of the Northwest Kidney Center in Seattle; Professor of Medicine at the University of Washington, Seattle; past president of the Renal Physicians Association; and past chairman of End-Stage Renal Disease Network Coordinating Council No. 2. I am testifying today on behalf of the Northwest Kidney Center and also on behalf of Dr. Belding H. Scribner, Professor of Medicine at the University of Washington, Seattle.

We would like to thank the Subcommittee for this opportunity to submit our comments related to the proposed prospective reimbursement rates for the End-Stage Renal Disease (ESRD) Program. The area we wish to address in particular is home dialysis in light of the objective of Congress and the Health Care Financing Administration (HCFA) to encourage further use of home dialysis. In our response submitted to HCFA regarding the proposed regulations, we have expressed our serious concerns about the data and the methodology used by HCFA to develop the proposed rates (1). In this testimony, we will address problems that we see with the proposed regulations related to home dialysis and discuss some actions which could be taken to alleviate these and other problems. As you know, the state of Washington has maintained a very significant home dialysis population for many years, and we remain convinced that home dialysis is the preferable form of therapy for a very significant proportion of patients and that it is safe and cost-effective. Our comments are based on our experience and that of others who have experience with home dialysis (Attachment 1).

SELF-CARE DIALYSIS TRAINING RATES

A major problem with the ESRD Program has been the lack of continuity of HCFA staff involved with the program. Illustrative of this is the statement in the proposed rules that self-care dialysis training has always been reimbursed at a screen level set $20 above the screen level for outpatient maintenance dialysis. In fact, in 1973 the rate for training dialysis was $190 per dialysis ($40 above the screen level). The proposed rate in the new regulations is unrealistic and bears no relationship to the experience of self-care dialysis training facilities. Although HCFA has not audited self-care dialysis training costs specifically, they must have information from programs such as ours which have an exception for reimbursement for training dialysis at a rate significantly higher than that proposed. We estimate that in our program home hemodialysis training costs $2,000 per patient over and above the cost of maintenance dialysis for the same period of time. The recent report by the Orkand Corporation (2) included a survey of a number of home dialysis programs and showed that the cost of a training dialysis was between 2 and 2½ times the cost of a regular maintenance dialysis. This same survey also showed that within a year the added costs associated with home dialysis training had been offset by the saving from use of home dialysis. If it is the intent of HCFA to encourage the use of home dialysis, it is essential that home dialysis training programs be adequately reimbursed for their services. The rate proposed is insufficient, will not be acceptable to existing training programs, and will be of little help to facilities wishing to start new training programs. HCFA should increase the rate appropriately or consider using cost reimbursement rather than prospective reimbursement for home dialysis training in order to ensure adequate coverage and to provide an incentive to facilities to undertake home dialysis training. HCFA should obtain information on the cost of training as a matter of urgency.

IMPACT ON HOSPITALS

Under the proposed regulations, in addition to other problems, hospital facilities are penalized by the rate-setting methodology for the fact that the home dialysis rate for patients followed by hospital facilities is 23.5% as compared with 10.5% for independent facilities. This and the other problems with the methodology and resulting reimbursement for hospital facilities are important because, as HCFA data clearly shows, hospitals are the site of many of the existing home dialysis programs. Excessive financial pressure on hospital facilities may result in their closure or their acquisition by proprietary dialysis corporations, both of which events are likely to have an adverse impact on home dialysis. As presently proposed, the methodology results in a very significant decrease in reimbursement to hospitals below their present costs, while at the same time, despite some reduction, continues to reimburse independent facilities at some $20 above their costs. In addition, because of the use of an area wage index, the proposed rates are lowest for hospitals in rural areas where home dialysis is often more common and are highest for free-standing facilities in major cities where the home dialysis rate is often lowest. We fail to see how these reimbursement rates will provide a significant incentive to free-standing facilities to increase their use of home dialysis, although they will cause serious problems for some hospital programs. Thus we strongly urge the need for a transition period of 6 months to a year to enable hospital programs to adjust their operations, and this will also allow time for other problems with encouraging a greater use of home dialysis to be resolved.

HOME DIALYSIS TRAINING FACILITIES

According to the notice of proposed rule making, 10 facilities support 30% of the home dialysis patients in the United States, and the home dialysis rate for proprietary dialysis facilities is significantly less than 10%. Presumably there are several hundred dialysis facilities which do not have home dialysis training or support programs. We believe that HCFA does not understand the problems of providing home dialysis on a larger scale throughout the country. In particular, HCFA appears to assume that any facility can send patients home and provide support as soon as these regulations are implemented. This implies that HCFA does not realize that home dialysis training and support requires considerable expenditure of effort and experience which is different to that required for maintenance outpatient dialysis. The provision of efficient outpatient dialysis treatment does not necessarily depend on the coordination with other supporting services to anything like the same degree as is required for successful home dialysis which, in addition to physician follow-up, also requires follow-up support including nurse and technician consultation, social work, dietary counseling, equipment service and repair, and provision of supplies. We do not believe that adequate home dialysis training and support programs can be developed on a crash basis by the large number of facilities presently not providing these services, and yet the proposed rules imply that this is expected as a result of financial pressures resulting from the proposed rates. If facilities that lack experience with home dialysis have to develop programs in order to remain financially viable, the danger is that this will be likely to result in poor quality training and inadequate support of patients. This in turn will lead to unsuccessful home dialysis, the return of patients to outpatient dialysis at increased expense, and consequent disenchantment with the use of home dialysis. We recommend that consideration be given to means of encouraging the regionalization of home dialysis training and support services (Attachment 2). This means that with a reimbursement system such as that proposed, a mechanism must be developed whereby facilities can enter into revenue-sharing affiliations so that those which elect not to develop their own training and support programs may receive ongoing financial support for referring their patients to home dialysis programs at other facilities.

HOW MANY PATIENTS CAN DO HOME DIALYSIS?

HCFA has suggested that 30% to 40% of all patients eventually may be treated by home dialysis, as compared with the present 15%. Based on our experience in Washington State, we believe that this is certainly feasible but that it would be unwise to expect such a change to be other than a slow one. Our experience has been that patients who have been treated by outpatient dialysis for some time become dependent and are difficult to persuade to undertake home dialysis. Consequently, the intent of the new regulations should be to increase the use of home dialysis by new patients, and this is a further argument in favor of a transition period prior to implementation of the proposed rates. In the recent Orkand Report (2) medical directors interviewed believed that at least 60% of their dialysis patients had no medical contraindication to home dialysis.

COINSURANCE FOR HOME DIALYSIS

A possible problem with the composite rate is that home dialysis patients will be faced with paying significantly higher coinsurance charges than is presently the case, even though for many this will be covered by private insurance or from other sources. Some of our own patients have already expressed concern about this with target rate reimbursement because those who have been on home dialysis for some time know that the actual cost of home dialysis is appreciably less than reimbursement to the facility with the target rate. This difference will be even greater with a composite rate. Such patients have expressed strong feelings that any margin accruing to the facility from reimbursement for home dialysis should be applied at least in part to helping home dialysis patients. To use this to support the facility in treating patients by outpatient dialysis, many of whom would be capable of home dialysis, is regarded as a questionable and discriminatory practice.

100% MACHINE REIMBURSEMENT

The proposed rules would eliminate the option of the 100% purchase provision for home dialysis machines which was legislated 4 years ago as an incentive for home dialysis programs and patients. We question the statutory authority of HCFA to abolish this provision by proposed rules, and we believe it should be reinstituted. HCFA comments that so far only about 10% of home dialysis patients use machines purchased under the 100% reimbursement option. However, there was considerable delay by HCFA in providing instructions for implementation of this option, at least initially the restrictions and paperwork for the facility were excessive, and facilities may have elected to continue existing arrangements for those patients already at home. HCFA should obtain more information on the experience of those facilities using the 100% reimbursement option and should enquire about the reasons why other facilities have elected to continue leasing or renting machines.

HOME DIALYSIS SUPPLIES

The proposed regulations permit patients to continue to deal directly with suppliers as an alternative to obtaining their supplies through a facility. This is a serious mistake and will prove to be inefficient and costly and will limit the ability of the facility to monitor the cost and quality of the supplies provided. Certainly, if the composite rate is to be effective in encouraging home dialysis, this provision should be eliminated.

HOME DIALYSIS AIDES

The use of paid home dialysis aides and the reimbursement of family members to assist with home dialysis has been shown to increase the utilization of home dialysis (2). Those of us with experience with paid home dialysis aides realize that they are useful in enabling some patients to undertake home dialysis who lack suitable family support. We are concerned that while the composite rate will permit use of surplus funds to support home dialysis aides, as does the target rate, the cost of such aides will be excluded from future rate-setting calculations. We believe this to be a mistake.

PERITONEAL DIALYSIS

There are two significant problems with peritoneal dialysis in the proposed regulations. First, HCFA proposes to reimburse outpatient intermittent peritoneal dialysis (IPD) at the same rate as for hemodialysis, claiming lack of cost information on outpatient IPD. This despite the fact that programs such as ours have been giving HCFA information for 10 years that IPD costs more because of the cost of the supplies and equipment and the longer duration of dialysis. It is hard to believe that after auditing 110 facilities and also considering exception requests over the last 10 years, no information has been gathered on to the cost of IPD, particularly as HCFA expressed concern about their lack of this information in their original reimbursement regulations. This information should be gathered urgently because both IPD and CAPD are effective forms of home dialysis for selected patients.

Second, it is remarkable that HCFA has only just begun to consider the cost of CAPD which has been publicized as a cost-saving modality of treatment for the last 3 years. Some have questioned how CAPD can be inexpensive when one considers the present price of fluid and supplies and the rate of peritonitis, hospitalization, and drop-out. Certainly, it is inappropriate for HCFA to express a preference for CAPD in the proposed regulations without having considered the data now available. Recent data from both the European Dialysis and Transplant Association and the National Institutes of Health CAPD Registry has shown the frequency of peritonitis and hospitalization and the very significant drop-out rate of patients from CAPD. This suggests that if used on a wide scale, CAPD should be regarded as a relatively short-term therapy.

Our position with regard to CAPD and IPD is that both are useful and appropriate forms of home dialysis for selected patients, and approximately 10% of the home dialysis patients in our program are treated by each of these treatments. Because of the high drop-out rate, we believe that CAPD should be used only for selected patients who are compliant, compulsive, and will adhere to the regime closely. The rapid growth of CAPD in the last 3 years has been responsible for most of the increase in home dialysis in the United States, but no information is available as to what happens to patients when they drop out from CAPD. Do they go back to outpatient hemodialysis or do they go to home hemodialysis? Only time and further experience will clarify the true role of CAPD, but this will almost certainly be less than the enthusiastic early reports suggested.

PATIENT INCENTIVES

Perhaps the most glaring omission from the proposed rules is the lack of provision of any patient incentive for home dialysis, even though physician and facility incentives are considered. We urge HCFA to consider possible patient incentives for home dialysis, preferably of a financial nature. The attendance allowance paid to home dialysis patients in Great Britain and by the Veterans Administration is one possibility, and others include a tax credit, a share in savings resulting from dialyzer reuse, or elimination of coinsurance for home dialysis patients.

PROPOSALS

As we have detailed, there are several problems with the proposed regulations which may limit the effectiveness of the proposed regulations in increasing the use of home dialysis.

With regard to prospective rate setting, we are strongly in favor of this approach to reimbursement, and we believe the composite rate approach to be an interesting one. However, we have to express our skepticism that this will have a major impact on the use of home dialysis. If composite rate reimbursement methodology had been used in 1973, this could have been very effective. However, in 1982, with 10 years of capital investment in dialysis facilities; with the training of a generation of nephrologists, many of whom have only experienced dialysis in lucrative outpatient dialysis centers and who have not been exposed to successful home dialysis programs; and with accumulation of a patient population, many of whom have not had the opportunity even to consider home dialysis as an option, the effect of the composite rate may not be as great as HCFA hopes for. If the rate is set at a level such as not to seriously inconvenience free-standing facilities, it is likely that many facilities presently without a commitment to home dialysis will be content with a lesser margin of profit and will hope to offset this by obtaining more patients as the result of the pressure on hospital facilities. Alternatively, if the rate is set at a level which affects many facilities adversely, patient care may suffer. Nevertheless, despite the problems, the composite rate approach is worth trying. However, we feel strongly that there must be a transition period rather than an abrupt change. This transition period before composite rates are instituted should be used to provide time for HCFA to develop revised regulations to better meet the needs of the ESRD Program and the intent of Congress.

Improved regulations will require:

1. Development of an adequate data-collection system. The most serious overall problem with the ESRD Program over the years has been the inadequacy of both the medical and financial data available to HCFA and the community. This problem must be resolved if appropriate decisions are to be made with regard to patient care and reimbursement. The Medical Information System should be reconstituted as a functional entity rather than data collection being the responsibility of 32 Networks, each collecting data independently. Financial data must be available in the payment files of HCFA, and ways must be found to make this available for analysis.

2. A mechanism for advice to HCFA both during the transition period and afterwards. We recommend the appointment of an advisory committee to HCFA to assist with development of revised proposed rules. The current proposed rules were developed during 1981 without significant organized input from outside HCFA and without discussion with the community during their development. We believe that an advisory committee working with HCFA would enable much better consideration of problems prior to publishing final regulations.

3. There should be a specific Office of End-Stage Renal Disease in HCFA. We urge Congress to press HCFA to reestablish such an office as the focal point to which physicians, providers, and patients can take their questions and problems and as an office where policy decisions can be developed by staff knowledgeable about the ESRD Program.

4. Generous reimbursement should be provided for self-care dialysis training and for intermittent peritoneal dialysis. The 100% machine purchase provision be reinstituted. Billing for home dialysis supplies should be through a facility rather than direct from patient to supplier. The cost of home dialysis aides should be included in rate-setting calculations. Appropriate cost and medical data must be accumulated on CAPD in order that its role can be more clearly established.

5. Finally, we urge the provision of patient incentives for home dialysis, preferably of a financial nature.

We realize the importance of cost-containment in the ESRD Program, as in other health care-related programs, but we are concerned because the changes which result from these regulations will set the pattern for the ESRD Program for several years to come. This being the case, we believe that if the intent is to encourage home dialysis it is essential there be time for consideration of the questions that we and others have raised. Time can be obtained by using a transition period during which the regulations can be reviewed by HCFA in the light of the many comments they have received and in conjunction with an advisory committee. As a result much better final regulations can be issued eventually. In the meantime, implementation of the existing provision that first-year reimbursement become the primary responsibility of major medical insurance where available, together with close scrutiny of existing exceptions, can provide significant cost saving.

Consideration must always be given to the long-term effects of any new regulations, as well as to the short-term cost savings. The proposed regulations have features which may encourage more widespread use of home dialysis, but we believe that significant changes in details have to be addressed if there is any hope for this to be achieved.

REFERENCES

(1) Letter to Dr. Carolyne Davis on BPP-126-P; Comments on the Notice of Proposed Rulemaking (NPRM), Medicare Program; End-Stage Renal Disease Program; Prospective Reimbursement for Dialysis, April 12, 1982.

(2) Evaluation of the Home Dialysis Aide Demonstration. TR-82W-012. Report by the Orkand Corporation. Contract #: HCFA 500-79-0054, January, 1982.

ATTACHMENT FOR THE RECORD.

PROBLEMS AND SOLUTIONS FOR HOME DIALYSIS IN THE 1980'S

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PROBLEMS AND SOLUTIONS FOR HOME DIALYSIS IN THE 1980'S

Home dialysis, including hemodialysis and both intermittent peritoneal dialysis (IPD) and continuous ambulatory peritoneal dialysis (CAPD), is a treatment option for patients with end-stage renal disease (ESRD) that has been shown conclusively to be technically feasible, psychologically rewarding, conducive to better patient rehabilitation, and financially less expensive than outpatient dialysis at a facility. The patient, with assistance of spouse, other family member, or paid helper, can be trained in the safe operation of currently available dialysis equipment. There is no evidence that with home dialysis the risk to the patient is greater or the incidence of complications differs from that for comparable patients treated by outpatient dialysis. In fact, home dialysis may be safer because of personal control of the treatment and the negligible risk of acquiring hepatitis. Psychologically home dialysis restores to the patient a sense of independence and control over renal failure and its treatment. As a result, and because of opportunity for flexible scheduling, the potential for patient rehabilitation is increased. Once home dialysis training has been completed and patients have had opportunity to dialyze at home, this method of treatment is preferred by the overwhelming majority of patients.

Implementation of Public Law 92-603 in 1973 resulted in a number of obstacles, financial and otherwise, to use of home dialysis, while at the same time financially encouraging use of outpatient dialysis. One result was a decline in home dialysis in the United States from approximately 40% of dialysis patients in 1973 to some 11% five years later. Many of these obstacles were addressed to varying degrees in Public Law 95-292, passed in 1978, which legislated changes in reimbursement for home dialysis (target rate reimbursement) and for outpatient dialysis (incentive reimbursement). It is now almost three years since that legislation passed, yet the target rate is only beginning to be implemented and the incentive rate is still only a proposed regulation. The last two years have seen a small increase in home dialysis, from 11 to 14% of the total patient population, although much of this increase probably relates to the rapid growth in use of CAPD. There is nothing to suggest that this increase relates to Public Law 95-292, and present information is that only a small number of existing home dialysis programs will elect target rate reimbursement.

This position paper has been developed by a group of concerned professionals and interested patients who are involved in home dialysis at different facilities throughout the United States. The intention is to delineate problems with support of home dialysis in the Medicare ESRD program and to propose some possible solutions. Despite the changing patient population of the last seven years, which has resulted in an increased number of elderly patients and those with complicating diseases, we believe that a significantly greater percentage of patients are capable of home dialysis than presently are being treated by this modality. This is particularly important at a time of increased concern about the cost of health care. However, we also emphasize that the financial advantages of home dialysis are only one issue, and that the greater opportunities provided by home dialysis for patient understanding, independence, and rehabilitation should make this the optimum choice of dialysis treatment whenever possible.

The potential for increased use of home dialysis has been illustrated recently by the choice of CAPD by almost a thousand patients nationwide in the last year. We believe that many of these patients saw CAPD as a means of escape from outpatient dialysis in programs where other forms of home dialysis were not readily available. Early estimates are that many of these patients may not remain on CAPD, and the long-term ability to sustain patients with CAPD is not yet known. This is in sharp contrast to experience with patients trained for home hemodialysis, as there are an appreciable number of such patients who have been dialyzing successfully at home for more than ten years.

ISSUES AND RECOMMENDATIONS

These issues and recommendations were developed by review and analysis of current problem areas. Unless specifically stated, comments apply to both hemodialysis and peritoneal dialysis and include CAPD where appropriate.

1. HOME DIALYSIS TRAINING:

The major problems in the area of home dialysis training related to misinformation, accessibility, attitude of physician, staff and facility administration, overabundance of outpatient dialysis stations, and present facility reimbursement for training.

a. Misinformation and accessibility: Many potential home dialysis patients enter and continue outpatient dialysis through lack of patient knowledge or as a result of physician, staff, and management bias against home dialysis.

Home dialysis training may be unavailable at a facility or in its geographic vicinity, and/or professional prejudice may prevent referral of patients for training.

All ESRD patients should have an understanding of all the various modalities of treatment and of the advantages and disadvantages of each as these pertain to them as individuals. In order to achieve this, simple standardized educational material should be available to all new patients, and each facility should have a means of providing patients with information regarding treatment alternatives available at that institution and those available elsewhere by arrangement. This must include clear information on opportunities for home dialysis and transplantation.

b. Physician, staff, and facility administration attitudes: A major factor operating against home dialysis often is lack of a positive physician attitude to this modality of treatment. There are many possible reasons for this, including the financial advantages of outpatient dialysis and lack of experience with home dialysis and of its effectiveness and safety. We recommend that physician reimbursement disincentives should be eliminated (see below).

Another significant reason for opposition to home dialysis, at least in some cases, appears to relate to physician ownership or interest in ownership of facilities. Consideration should be given to controlling this potential conflict of interest.

Staff attitude usually reflects physician attitudes. The attitude of facility administration also represents ownership and its possible conflict of interest.

c. Availability of dialysis stations: An important step to encourage home dialysis would be some constraint on continuing expansion of capacity for outpatient dialysis. This must be restricted, and expansion and opening of new dialysis units should be related to meeting an appropriate local goal for the percentage of new patients being trained for home dialysis.

d. Facility reimbursement for home dialysis training: Facilities undertaking home dialysis training should be fully and promptly reimbursed for all costs involved in training patients, including the full educational costs of the program. Current reimbursement is related to the number of procedures rather than to the procedures as part of the educational program. It would be preferable that the cost of training be reimbursed at the 100% level. Reimbursement methodology should allow for individual facility variation in training program and scheduling.

2. CERTIFICATION OF HOME DIALYSIS TRAINING FACILITIES:

Contrary to recently proposed regulations, we oppose certification of facilities providing only training (for any modality of home dialysis) and of training facilities which provide only self-care dialysis in the facility unless such facilities are part of a program providng all modalities of dialysis in a nearby related facility. Self-care dialysis in a facility is not clearly defined, can be used as a means of avoiding the issue of home dialysis, and is better achieved as a result of financial constraints on reimbursement for outpatient dialysis. We believe that certification of training-only facilities will lead to further fragmentation of the ESRD program. Training should be carried out only in renal dialysis centers or facilities meeting minimum utilization rates for training in order to take advantage of economies of scale and development of expertise.

We recommend that home dialysis training facilities be certified on an annual basis and meet existing Medicare standards as either a renal dialysis facility or renal dialysis center. Training stations in certified facilities should be exempt from the usual minimal utilization rate, and annual certification should require a minimum of training activity necessary for maintenance of expertise. This should be at least 12 new patients trained per year for home dialysis or CAPD, 6 per year for intermittent peritoneal dialysis, or if a facility provides training for more than one modality of treatment, a cumulative total of at least 20 new patients trained for home dialysis per year. Exceptions to these rates should only be granted on a geographic basis. Facilities must maintain records of training activities including information on the number of patients starting training, the facility the patients came from, the number of patients completing training, their disposition, and the success rate of the training program.

We recommend that a survey be made of training stations and related resources currently available. We believe that there are a large number of "training stations" not being used for training at this time, and that it has been a common practice for facilities applying for expansion to include such stations in their applications with no intention of using them for training purposes. If a survey records this to be the case, such stations should be decertified.

We recommend that consideration be given to establishment of regional home dialysis training programs. Successful training requires suitable space, staff, and materials, and is best carried out in a program training a significant number of patients annually. Too many centers give lip service to training and yet do not train patients. A regional center can train patients effectively and speedily, return them to the care of their referring physician, and provide coordination of all necessary support services. Such a regional center would be more feasible if it were able to provide travel and subsistence support to the patient and partner during training (see below).

3. HOME DIALYSIS SUPPORT SERVICES:

Provision of high quality, readily available support services is essential for the patient dialyzing at home. Continuity of medical care through a local nephrologist must be maintained, but in addition, there must be continuity of nonphysician professional and other support in order to maintain the environment permitting patient independence to prosper over the years.

Supplies, equipment, and equipment maintenance services must be provided either directly by the training facility or the training facility should insure these are provided by arrangement, either through manufacturers or the referring dialysis facility or center.

If provided by arrangement, the training facility must take responsibility for insuring the quality of services provided. In addition, nonphysician professional support, including social worker, dietitian, home visiting nurse, etc., must be provided directly by the training facility or by arrangement.

4. HOME DIALYSIS AIDES:

The use of paid home dialysis aides for patients wishing to dialyze at home and who lack a family member available or willing to assist has proved extremely helpful to some home dialysis programs. We recommend that use of such aides remain an option available to a home dialysis training program if desired. We recommend that HCFA not set standards for such aides, but rather permit individual facilities to set their own criteria for patient eligibility for an aide, payment mechanisms, and training. We believe that as a general rule, aides should not be nurses or technicians, except where required by State regulations, but rather individuals hired by the patient and trained to the same level as a family member. A facility should have the option to maintain a cadre of aides available to go to patient's homes as and when needed, but this should not be mandatory.

With regard to reimbursement, it is not clear that the present option of target rate reimbursement will provide sufficient funds for reimbursement of aides. Below we recommend other options for payment of aides and home dialysis which should be considered.

5. REIMBURSEMENT:

Reimbursement remains the major factor affecting where patients dialyze. The method of reimbursement instituted in 1973 had a severe impact on home dialysis which has never been overcome. We believe that in addition to potential cost-containment, home dialysis is the preferable form of treatment for many patients, and as such not only should any disincentives be removed, but incentives should be provided.

a. Reimbursement for home dialysis training: We recommend that facilities certified for home dialysis training be reimbursed on a cost basis for home dialysis training and for training of family members and aides rather than on a per-dialysis basis. This enables reimbursement for training activities not directly related to the patient's own dialysis and which are essential for a quality training program. In addition, we recommend 100% reimbursement for home dialysis training as an incentive to the facility.

We recommend that consideration be given to providing reimbursement for training by staff from a certified home dialysis training facility when this training is performed in a patient's home.

This would apply only in special circumstances, including training of hepatitis B-positive patients at home in order to minimize the risk of contamination of the facility.

We also recommend that consideration be given to the possibility of a mobile training program--nurse and materials--which could be reimbursed for going to a small unit in a geographically remote area in order to train a patient.

b. Facility reimbursement for home dialysis support services: In order to make target rate reimbursement more effective, we recommend that a limit be set on home dialysis charges billed by a facility on a per-dialysis basis if the facility does not elect the target rate option. Some facilities and suppliers are charging an excessive mark-up on dialysis supplies, thus making their per-dialysis charge for home dialysis greater than for outpatient dialysis. We recommend that a limit be set at (say) 10% below the national average charge for outpatient dialysis for such reimbursement.

In order to provide an incentive for facilities to use target rate reimbursement, we recommend that the facility have the option of sharing with the patient any surplus derived from the target rate, and that this sharing should be an allowable expense to the facility in their Medicare cost report. Similarly, any payments to spouse or family member for home dialysis services also should be an allowable expense to the facility.

We believe that the target rate, or any rate set each year for home dialysis reimbursement, must not be dependent upon the previous year's average outpatient dialysis reimbursement rate, but must be adjusted by an inflation factor such as an index of the increase in medical and other costs.

We recommend that consideration be given to the development of totally new methods of dialysis reimbursement, and in particular, the use of a uniform or composite rate of facility reimbursement for all dialyses, whether these are performed as an outpatient or at home. We believe that setting such a uniform rate at a level close to or slightly below the proposed incentive rate could be adjusted so as to encourage further use of home dialysis because of the potential for generation of surplus or profit.

Alternatively, we recommend examination of the target rate level and whether 70% of the outpatient rate is appropriate. The possibility of a phased-in new target rate, starting at say 95% of the incentive rate and decreasing by 5% per year while cost data and experience is collected, should be considered.

c. Reimbursement and the patient: It is essential that reimbursement for home dialysis should be adequate, and preferably this should be sufficient to provide incentive for the patient to consider home dialysis.

We recommend that all home dialysis training facilities use the 100% reimbursement option for capital equipment costs, either through the training facility itself or a nonprofit entity. This is presently available as an option, but mandating this would result in benefit to the patient without detriment to the facility.

We recommend investigation of the possibility of legislating a tax deduction for provision of dialysis services in the home by a family member or aide as a possible means of providing support to pay for an aide and, more importantly, to pay for services provided by the patient and family member. The recent introduction of S-3264 to amend the Internal Revenue Code to permit such a deduction for medical services in the home for individuals over the age of 65 is an example of such legislation. However, because a significant number of dialysis patients are of low income, the possibility of a tax credit for such patients should be considered. The potential advantage of this approach is a reduction in the target rate with support to patient and family coming from general tax funds.

As commented above, a facility should have the option of sharing with the patient any surplus derived from the target rate and also should have the options of paying a family member for home dialysis and of providing a paid aide if desired.

Payment should also be provided for travel and subsistence for patient, family member, and/or aide during home dialysis training at a certified training facility where the distance involved is greater than (say) 50 miles.

d. Physician reimbursement: We believe that a significant incentive for home dialysis would be provided by making physician reimbursement under the alternate reimbursement method (ARM) identical whether a patient is treated at home or as an outpatient. This would be more equitable than the present arrangement. If this is not done, we recommend strongly that the individual nephrologist be permitted to elect the ARM for home dialysis patients while continuing to receive fee-for-service reimbursement for outpatient dialysis patients. This would merely require a change of regulation but would provide a financial incentive to physicians.

Conclusion:

Home dialysis remains a desirable treatment entity for many reasons, and yet currently this is not being used as extensively as would be appropriate. We believe that some or all of the recommendations described would assist in encouraging home dialysis. Although these proposals will increase the cost of home dialysis, we believe that in the long term, the overall costs of the ESRD program will be reduced as compared to the cost of a national program based on the use of outpatient dialysis. We also believe that as a result of greater use of home dialysis, patient care and rehabilitation will be improved and more patients will be able to return to work and contribute to the general tax base.

We will be delighted to elaborate further on any of the above comments or recommendations at any time. We feel strongly that home dialysis is a more efficient and desirable method of dialysis treatment for many more patients than is the case at this time, and we would like to see incentives from the Health Care Financing Administration to permit this modality of treatment to be implemented on a competitive basis with outpatient dialysis.

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DEVELOPMENT OF A REGIONAL HOME HEMODIALYSIS TRAINING PROGRAM

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THE DEVELOPMENT OF A REGIONAL HOME HEMODIALYSIS TRAINING PROGRAM

A. The Problem - As everyone knows, home hemodialysis is lagging badly in the United States. Furthermore, past experience indicates that among the 50,000 plus patients already accustomed to in-center care, there is enormous resistance to changing to home care, and there is apathy and even active opposition from certain quarters to increasing the utilization of home dialysis.

B. Reasons for Failure - Clearly the present approach to the problem of increasing home dialysis is not working. Furthermore, recent HCFA data appear to indicate that among those centers attempting training for home care, the failure rate is very high.

At the same time, data from centers which are successful with home dialysis reveal that very specialized services and organization are required to operate a successful home hemodialysis program. Few centers presently have the capability or the resources to provide these essential services. Finally, it is quite apparent that unless a home dialysis program has a minimum number of patients to care for, it cannot maintain either the expertise or the necessary supporting services to do a quality job in a field where quality is a necessary prerequisite to success.

C. A Regional Home Dialysis Program - One, and possibly the only solution to this problem of increasing home hemodialysis in the United States is to develop a network of hemodialysis centers which are designated as regional home dialysis training and support centers.

D. Characterization of a Regional Home Hemodialysis Training and Support Center - A regional center will have the following capabilities:

1. A multidisciplinary planning process to assure consideration of necessary information to allow for optimal patient rehabilitation on home dialysis.
2. Medical and nursing direction/support to assure qualified staff, pertinent program content, and appropriate dialysis equipment.
3. A program designed to assist patients to identify the primary learner, be this patient, family member, or nonfamily member.
4. Training staff comprised of nurses and possibly technicians.
5. a. A training program which is educationally sound and individualized to patient needs, including assessment of learning capabilities, stated objectives, training schedule, lesson plans, and evaluation process.

   b. This training program should not only be available for initial training but should have capability for retraining as well; i.e., new helpers, new equipment, change of access, or refresher training.
6. Administrative support for processing of training materials, necessary record keeping, and financial coordination.

7. Supportive working relationship with the patient's physician to provide appropriate medical input to the patient's plan of care and to ease the transition between dialysis environments.

8. Dietitian support to assess nutritional needs to assure proper understanding of diet regimen as well as to provide support or assist with problem areas during training or as the patient is at home.

9. Social work support to facilitate patient logistics surrounding training; i.e., transportation, lodging, care of other family members, etc.; to provide emotional support throughout the course of training; to assist the patient in adjustment to home dialysis and maximum rehabilitation, including vocational; and to be available to patients on home dialysis for psychosocial and/or financial concerns.

10. Counselors (may be done by social workers; to assist patients with financial plans/problems/concerns surrounding home training and home dialysis.

11. Technical support to assess and advise regarding home alterations, to assist with equipment and water treatment installation, and to provide expertise for equipment repair and follow-up as needed.

12. a. A review mechanism that at least monitors, assesses equipment (dialysis and water treatment) safety and function in the home environment, assures patient possession of current appropriate procedures, and provides feedback on dialysis-related problems.

    b. A program for visitation which permits assessment of the patient in the home environment, assessment of the technical and procedural aspects of dialysis as performed by the patient, and provides follow-up or referral for problem areas as necessary.

13. A system for provision of dialysis supplies to the home that minimizes patient involvement to the degree possible.

14. Facility dialysis to allow backup for medical, technical, or social reasons, including respite from home dialysis.

15. Resources to allow the patient to maximize benefits of home dialysis and rehabilitation including: (a) facilitation of arrangements for vacation dialysis be this in a center using portable equipment or assisting patients to arrange to move their own equipment; and (b) a communication network to keep home patients apprised of changes in routines, procedures, equipment/supply items, and common problems.

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Chairman **Rangel**. Thank you.

I think that most of the testimony that we have taken this morning, that you are in accord with each other as relates to the regulations.

Do any one of you want to take advantage of this opportunity to ask Dr. Blagg questions as it relates to home dialysis?

[No response.]

Chairman **Rangel**. Doctor, when you talked about physicians all receiving one reimbursement rate, it is not the physician in a lot of cases that gets the reimbursement, so how would you work that out, whether the physician was treating someone at home or treating someone at this clinic.

Dr. **Blagg**. I was speaking specifically about the physician fee. In the new regulations, as you may have noticed, the alternate reimbursement method, which is a global monthly fee which currently is paid at two separate rates, higher if the patient is in the center as opposed to the home, is equalized. I agree with that concept. The important issue is that one concern physicians have had throughout the course of the ESRD program is that this global fee mechanism or ARM, is the only medical physician fee that is not updated annually related to the medicare index. That that should be looked at.

Chairman **Rangel**. I hope that you might make yourself available if in fact the administration is willing, and it just seems to me that the administration believes that home dialysis can provide quality care at less expense, and they are using a financial incentive mechanism to do this. They do not know, we do not know, you do not know just what motivates people, but we all know that the patients are scared as hell that they are going to be denied treatment.

It would seem to me that if you could share with certain people in the administration the basis of your experience as to how we can do what, obviously, you have done successfully, and the administration could reach its goal, that it might avoid the confrontation and it might allay the fears of some patient that regardless of what political or fiscal decisions are being made, that they would not be adversely affected.

Chairman **Rangel**. Mr. Martin?

Mr. **Martin**. Thank you, Mr. Chairman.

I appreciate your welcoming me back to the hearing of the subcommittee.

Chairman **Rangel**. I am glad you were able to come back. [General laughter.]

Mr. **Martin**. Mr. McFeeley, hospital based facilities, I understand, have about 24 percent of their patients on home dialysis, while independent facilities such as yours, and others that you are here to represent, have about 9 percent of their patients on home dialysis.

Is there some particular reason for that? Is that because of your patients cases being more complicated? Earlier we heard the reverse, that the hospitals have a more complicated patient profile than yours.

What is the reason for that?

Mr. McFeeley. I do not think the patient mix in terms of diagnosis is different. There are certain geographic differences, and those geographic differences as to where the centers are located translate into familiar family and social problems. They may not be medically different, but they may not have a person at home that can help home dialyze.

But more importantly, I would say, as a——

Mr. Martin. But that person would be no more likely to come to your facility than to a hospital, would they?

Mr. McFeeley. Well, I think that you will find that people in urban areas oftentimes will not have that kind of stable familiar relationship or will not have a home that is suitable for home dialysis that you might find in a less congested area.

But I think there are other reasons. I think that is one reason. I think the other reason I explained earlier was the fact that many of our centers get their patients from hospital referrals. The patients come from the hospital which home trains the patients who are best candidates for home training. So, the patients that we get have already been screened for home training. We in a sense participate in the home training program, but our facilities, several of our facilities might not have a separate home training. We are going along with in many areas what Dr. Blagg was talking about in terms of regionalization. It would be inefficient for or centers to duplicate what our referring hospital has been doing. Therefore, the referring hospital gets the credit for having the home patient trained because that patient has never come to our center.

Mr. Martin. Do you feel that there is any incentive for your center to encourage patients to do home dialysis?

Mr. McFeeley. Yes. I think that one thing has to be pointed out, that National Medical Care owns and operates one of the largest supply companies for home dialysis. We are in the business of supplying home patients, and we have all kinds of incentives for increasing the home patient population and servicing those patients at home.

Mr. Green. May I comment on this?

Mr. Martin. Yes, sir.

Mr. Green. First of all, I think we should do more home treatment than we are doing. I do not have a good answer as to why our percentage is lower. I suspect it is because the doctors are not motivated to deal with the patients at home and to provide an incentive for the independent center to provide home treatment. I am not clear exactly how that will work. It seems to me it is up to the doctor and the patient and not the business organization to make that decision.

Mr. Martin. Would that not also be true of the hospital?

Mr. Green. Yes; it would be. Therefore, the composite rate is an experiment. Maybe it will work. I think it is worth a try. But I am very unclear as to where it is placing the incentive, if it is on the right party or not.

Mr. Martin. Do you suggest it ought to be on the patient, then?

Mr. Green. I think the doctor, that is a matter for the doctor and the patient to decide, and if the doctor is motivated in the direction of home treatment, as Dr. Blagg obviously is, you will see a lot more home treatment. To give the center more money because they have more home patients is confusing I think.

Mr. MARTIN. What would you do to encourage the patient? Provide a copayment requirement for the more expensive service, or maybe split the saving with them if they take home dialysis?

Mr. GREEN. Well, that has been suggested by the Republicans on the Senate Finance Committee, that you give a bounty to the patient. That does not strike me personally as the best approach.

Mr. MARTIN. You would rather give the bounty to the hospital?

Mr. GREEN. No; to the doctor. I think it is more inconvenient for the doctor to see patients spread all over in a variety of locations than in a single location. The fact is I am not sure the doctors will go for more home treatment unless they are paid a bonus for the inconvenience.

Mr. MARTIN. I was told by an earlier witness, Dr. Thompson, that there is in the new regulations a provision for a charge that would be paid for the hospital or service to home dialysis patients, and I guess what you are saying is you might split that or provide similar appropriate payment to the doctor for seeing those patients?

Mr. GREEN. The composite rate is based upon the assumption that home treatment without a paid assistant is less expensive, and even though it is less expensive you receive the same amount as you would for an in-center patient, and therefore the center, if it is not owned by a doctor, would theoretically have an incentive, but the center does not make the decision. The doctor makes the decision.

Now, if the doctor owns the center, then you have got it set up just fine.

Mr. MARTIN. But you are saying, then, for the doctor who does not own the center, that you ought to have a payment for the doctor. Is there not one now allowed for the doctor?

Mr. GREEN. I think the incentive should be given to the doctor rather than the business organization for this particular issue.

Mr. MARTIN. Do you agree with that, Dr. Blagg?

Dr. BLAGG. I am not sure that you should give a specific incentive to the physician. I think that if you pay the doctor the same for all patients, this would be an incentive in itself. The global fee or ARN at present covers all services provided over a month for patients dialyzing in-center, and the patients vary widely as to whether they are sick or otherwise. Why not include the home patient in this, too, so that there is just one flat monthly rate for all patients, wherever they are treated? That certainly would result in an increase over what physicians are paid at the present time for home dialysis patients, and so would be an incentive in that sense. I do not think you have to pay the doctor more for sending patients home than he would get for patients at the center.

Mr. MARTIN. Just pay them the same?

[Dr. Blagg nods in the affirmative.]

Mr. MARTIN. Mr. Chairman, I have no further questions.

Chairman RANGEL. Thank you very much.

And Dr. Blagg, if you do have some time before your return to Seattle, the committee would like to discuss with you further how perhaps we can get the benefit of your experience.

Dr. Carolyne Davis, the Administrator of the Health Care Finance Administration.

It is good to see you again, Doctor. Congressman Jim Broyhill was here to visit with you and asked me to welcome you on his behalf.

Ms. **Davis**. Thank you.

Chairman **Rangel**. I want to thank you and the administration for your stringent efforts at containing costs, especially as it relates to end-stage renal disease. Congress has been very concerned about how we can protect as many patients as possible and still have it cost effective without affecting the quality of care.

I think it has been generally recognized that for those patients who lend themselves to home treatment, that it is less expensive and provides a family setting, and we professionals would like to encourage that.

It would appear to us that the reimbursement method is one of the few tools we have to direct people to do those things. Unfortunately, what has occurred is by the administration proposing the regulation an educational effort was made to allow many people to believe that centers would be closing. Unlike clinics, to many people this is a question of life and death.

Those of us who were elected had no way of knowing whether the administration was right or wrong, and we were not in a position to advise our constituencies. We were not in a position to talk with doctors and patients, to tell them what the effect would be. And the reason we were not in that position is because it never came before the Congress. I hope the Congress never attempts to tell the administration how it should administer programs, but I certainly hope that regulations would not be used to legislate.

There are some people who believe the data you used—well, you have heard all of the questions raised. I will raise them for the record, that we may not achieve the goal we want to achieve, that is, providing more incentives for people to have home dialysis, that the data being used is really old data and that while we all agree to the goal, the regulations ought to be withdrawn and more input should be had by the providers of the services.

The purpose of these hearings is not to be critical but to try to assure the American people who have some concern about these patients, where the question is not political but life or death, that we are not going to move until collectively the Government can give assurances they will be protected.

And for those reasons, I appreciate your patience with me and the subcommittee, and I do hope your testimony can give those types of assurances.

I hope you have heard some of the witnesses who have been very successful in doing what the administration wants to be done. They have ideas. I hope the administration is willing to sit down and try to work out something with them.

Mr. Pickle?

Mr. **Pickle**. Mr. Chairman, I have no questions. I have just returned to the committee. I was not able to hear Dr. Davis.

Chairman **Rangel**. She has not started yet.

Mr. **Pickle**. You have not?

Ms. **Davis**. No.

Mr. PICKLE. Then I will listen. I thought Mr. Rangel was making one of his summations. [General laughter.]

He summarized before you started then. [General laughter.]

STATEMENT OF CAROLYNE K. DAVIS, PH. D., ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY ROBERT STREIMER, ACTING DIRECTOR, OFFICE OF COVERAGE POLICY, BUREAU OF PROGRAM POLICY; AND MARTIN KAPPERT, DEPUTY ASSOCIATE ADMINISTRATOR FOR OPERATIONS

Ms. DAVIS. Thank you, Mr. Chairman.

Let me just begin by introducing my two colleagues who are with me. On my left is Mr. Robert Streimer, the Acting Director of the Office of Coverage Policy in the Bureau of Program Policy; and on my right is Mr. Martin Kappert, who is the Deputy Associate Administrator for Operations.

Let me begin by assuring you that the administration, too, is very concerned for the welfare of the individual end-stage renal disease patient, and we have kept that in mind as we have developed these regulations. We had extensive discussions with many members of the community, and indeed, many of today's witnesses we conversed with at great lengths before developing these regulations.

Of course, the purpose of an NPRM is to solicit further comments. We are now in receipt of a number of comments, and we will be taking these comments into consideration prior to the development of a final regulation.

Let me just briefly summarize the written testimony that you have. As you well know, the legislation that established the end-stage renal disease program provided HCFA with the charge of administering that program, and we developed the following goals and objectives.

First and foremost is to insure that the beneficiaries do receive the care that they need; and to encourage the proper access to resources while maintaining the quality of care; to provide also for the efficient delivery of the appropriate type of care by physicians and facilities, and to encourage self-dialysis or transplantation for the maximum number of patients that are suitable for those therapies.

Let me begin first with a small history relative to the growth of the program. I think it is helpful. As you can see on chart I, the number of hospital-based facilities has remained somewhat stable, 536 facilities in the beginning of the program at the top line, and in 1981 there were 654 facilities. However, the large growth has been the free-standing facilities in which there has been a very dramatic growth. Initially, 68 facilities in 1973, compared to 466 facilities in 1981.

Let me also call your attention to our pin chart which is——

Mr. PICKLE. Dr. Davis, by the independent facilities, do you mean this as home dialysis?

Ms. DAVIS. The free-standing facilities.

Mr. PICKLE. Say it again.

Ms. DAVIS. Non-hospital.

Mr. **Martin**. But not home dialysis.

[Ms. Davis nods in the negative.]

Ms. **Davis**. The home dialysis population is a separate one. The home dialysis patients would be those patients who could be referred from either type of facility, either the hospital or the free-standing facility.

The large chart is a record of the exact distribution of all the facilities nationwide. The pin chart representing each and every facility that is available for some form of dialysis therapy. We will be happy to leave that for the committee to study later.

Let me move on, then, to the growth in the beneficiary population because this has been significant over the years.

The next chart illustrates very clearly the significant increase from 18,400 beneficiaries in 1974 to more than 60,000 by the end of 1981, roughly three and a half times the original number, or an average annual rate of increase of about 20 percent.

I would also point out that now the program covers the reimbursement for roughly 93 percent of all end-stage renal disease patients, and the costs, too, as you can see, have grown from $229 million in 1974 to about $1.6 billion in 1981.

I would like to recall for all of our benefit that the beneficiary population receiving benefits in the end-stage renal disease program represent less than one quarter of 1 percent of all of our medicare beneficiaries. However, they do account for about 10 percent of all of the part B reimbursement dollars.

Obviously the growth in the number of beneficiaries is indeed one major factor in the increase in the program costs. Currently, our medicare reimbursement rules, we believe, are also partly to blame. If the rules are not changed, we anticipate that the costs can rise to about $2.4 billion by 1984.

Let me briefly review the current Medicare reimbursement rules. Hospitals are reimbursed retroactively for reasonable costs. This method, we believe, offers very little incentive for increased efficiency. Free-standing facilities are reimbursed their reasonable charges, up to a maximum rate of $138. And nearly all of those facilities do claim the maximum rate. All of the facilities are able to keep the difference between their charges and their costs. This gives them an incentive to operate efficiently.

The audited data that was analyzed in 1981 show that the median cost per in-facility dialysis was $135 for the hospital-based facilities and $108 for the free-standing facilities, while the audit data shows a median cost for the home dialysis treatment of $97.

We do believe that home dialysis is suitable for some 30 to 40 percent of the patients, and yet actually it is only used for approximately 17 percent of patients nationwide.

The next chart will indicate rather clearly that there is very wide geographic variations. For example, the chart indicates that the State of Washington has a rather high rate for home dialysis of 54.2 percent. Contrast that with the State of California with 9 percent.

Let's look at another two States which are geographically side by side in the middle of the country. One would look at the chart and see that Illinois has a rate of 6 percent while the adjacent State of Indiana has a home dialysis rate of some 43.9 percent.

We also ought to recall that before the end-stage renal disease program payments were initiated by the Federal Government, the rate of home dialysis was running approximately 40 percent.

I would like to move on now to the audit discussion.

In March 1980 we selected a stratified sample of facilities and audited 38 free-standing facilities and 67 hospitals, roughly, 13 percent of all the operating facilities. These audits were to be used for establishing rates. This had been mandated by the 1978 ESRD amendments.

Before we could implement the rates from the 1978 amendments, the Omnibus Budget Reconciliation Act of 1981 was passed, and that Act indicated clearly a preference for a composite rate. In order to determine a composite rate we had to identify the costs of home dialysis, and so 25 of the largest home dialysis programs were audited last fall in cooperation with the Inspector General's Office.

As I indicated earlier, the 1981 act did specify a preference for a separate composite rate for the hospitals and the free-standing facilities. Since the same rate is to be paid for both the home and the in-facility dialysis, the rate would give the facility a financial incentive for each patient who is dialyzed at home.

Let me go on to summarize the description of our methodology. The next chart summarizes the rate calculation. We would use as a departure point the median costs of the home dialysis, $97, and the median cost of in-facility dialysis, $126, for all our audited facilities. These costs would then be weighted by the proportion of the patients dialysing in each of the locations. The hospital base is 76.5 percent for in-facility and 23.5 percent in the home. For the free-standing, 10.5 percent at home and 89.5 percent in facility.

We would also raise the hospital rate by an additional $2.10 to account for the apparent excess in the overhead costs that do result from our medicare accounting requirements.

Our initial studies would indicate that there was no evidence to justify a hospital's higher costs for either their labor or their supplies. However, we did add a 5 percent factor to the hospital rate to account for the possibility that our methodology may not have fully recognized some of these costs, or that the data itself might have been somewhat aged.

The conference committee report language had indicated clearly we were to use a wage index. We selected the Bureau of Labor Statistics data for want of any other wage index. The average payment rate for the hospital-based facilities would then be $132, and the range would be from $114 to $148; the average payment rate for the independent facilities would be $128 with a range from $109 to $143.

We recognized the need for exceptions and we had clearly indicated in the NPRM that we would offer a higher rate for those facilities with justifiably higher costs that would be attributable to atypical patient mix, to isolated facilities, which are the sole provider in the area, under extraordinary circumstances such as flood, fire, things of that nature, or for additional costs attributable to the educational component.

Moving on to the physician reimbursement, currently the physicians are paid under either the initial method or the alternative reimbursement method. These methods provide, we think, disincentives for the physicians to treat patients on home dialysis. Under the initial method there is no allowance made for the general supervision of the home patient. Under the ARM's method, the average monthly fee is approximately $220 if the patient is in-facility. However, it averages about $154 per home dialysis patient.

In order to remove the physicians' disincentive to treat home patients, we propose to eliminate the initial method and to pay equal capitation payments, averaging approximately $184. This would include both the in-facility and the home dialysis patients.

Let me address the home dialysis equipment issue. The program can now reimburse a qualified facility, or State ESRD program the full cost for their home dialysis equipment. We propose to discontinue this option because the composite rate would frequently have to be adjusted in order to account for the prior reimbursement. Any equipment that was purchased, however, before the effective date of composite rates would be handled under the terms of the established agreement and we would simply make an appropriate adjustment for those facilities.

Let me then move to some comments on the proposed regulations. The comment period has just ended. It ended April 13, and we are now analyzing roughly 2,100 comments that have been received. Let me indicate clearly that we do appreciate the letter that we received from Chairman Rangel expressing concerns, and we will take those into consideration as we analyze our final comments.

There were a number of areas that the comments addressed. First was concern for reduction in access and quality of the care. A great many of the comments expressed concern that the facilities would close, or that there would be reduced staff, and that this would significantly reduce the quality of care.

Now, we obviously cannot guarantee that no facility would close, but we believe that with the exceptions process we could prevent disruption of services. We also will work with the facilities on identifying problems. Of course, we would not allow facilities to participate if they do not meet quality of care requirements.

I think perhaps commenters did not fully understand that we would be paying a composite rate for all home treatments, too, and that this would impact upon the overall rates.

Comments were received relative to the rural facility rates. In establishing the wage index, we felt we were being responsive to congressional intent. However, we do realize that the comments that we have received indicate that we perhaps need to review those comments on the index for the wage for the rural facilities. And we will look at that to determine whether or not any adjustment needs to be made.

In terms of the hospital rates, commenters claim that the hospital rates should be higher because the patients receive more care than those in the independent facilities, or in other words, that hospitals had a sicker patient mix. Before we could determine those rates, we looked before we found no difference in the data that relates to the case mix. Because we consider this a very important issue, we have directed our Office of Research to complete a new study to look at the data to determine whether or not a difference does exist that would warrant making a change in the rate or an adjustment in the methodology, and I anticipate that the results of that study should be back to us by about the middle of May.

Mr. PICKLE. How long has that study been going on?

Ms. DAVIS. About 60 days, sir.

The comments relative to the home dialysis I think primarily expressed concern that the new system would pressure patients perhaps unsuitably to go on home dialysis. While we do want to encourage home dialysis, we do believe that the patient must be judged by the physician as to whether or not they are medically and psychologically suitable for home dialysis.

We recognize that for hemodialysis the patient must also have a reliable partner and sufficient room and features that would need to be covered in the home, and that all home dialysis patients would obviously need to complete a successful training period.

Just as soon as we have completed the analysis of the comments to determine if there are needs for changes, we will move to publish our final regulations.

I would like to point out that this will undoubtedly take us several months because we have an extensive number of comments to analyze. We anticipate it will take us about 6 to 8 weeks to do that, and then follow that with the development of final regulations.

Let me also point out that while we believe the facilities have had a considerable time to plan for the reimbursement changes, that the issue has been raised relative to the concern for the need for a transition period, and we will be sensitive to that as we look at the final regulations.

In closing, I want to simply reiterate that we do believe that the proposed system that we have developed meets the statutory requirements that the payment rate should be prospective, composite, and that it should provide an incentive for home dialysis. We believe that the new system will be a benefit to all of the parties—to the Federal Government through our lower expenditures or reduction in rate of growth; the facilities through the potential for added profits; and to the patients for having more opportunities for home dialysis.

We are indeed, however, committed to a careful review and analysis of all the comments that we have received.

Thank you, Mr. Chairman. I would be happy to answer your questions.

[The prepared statement follows:]

Statement of Carolyne K. Davis, Ph. D., Administrator, Health Care Financing Administration

MR. CHAIRMAN, I AM CAROLYNE K. DAVIS, THE ADMINISTRATOR OF THE HEALTH CARE FINANCING ADMINISTRATION (HCFA). WITH ME TODAY ARE ROBERT STREIMER OF THE BUREAU OF PROGRAM POLICY AND MARTIN KAPPERT, DEPUTY ASSOCIATE ADMINISTRATOR FOR OPERATIONS.

WE ARE PLEASED TO BE WITH YOU TO DISCUSS THE MEDICARE END-STAGE RENAL DISEASE (ESRD) PROGRAM. AS YOU REQUESTED, I WILL FOCUS MY DISCUSSION ON OUR PROPOSED REGULATION GOVERNING REIMBURSEMENT OF ESRD FACILITIES AND PHYSICIANS.

INTRODUCTION

ALMOST TEN YEARS HAVE GONE BY SINCE CONGRESS AUTHORIZED THE END-STAGE RENAL DISEASE PROGRAM. IN PASSING THE LEGISLATION, CONGRESS STATED THE PROGRAM'S MISSION: TO ASSURE THAT PATIENTS WITH END-STAGE RENAL DISEASE HAVE ACCESS TO HIGH QUALITY, COST-EFFECTIVE MEDICAL CARE. IN KEEPING WITH THIS CONGRESSIONAL INTENT, HCFA HAS ESTABLISHED THE FOLLOWING GOALS AND OBJECTIVES FOR THE PROGRAM:

o TO ENSURE THAT BENEFICIARIES WHO HAVE BEEN DIAGNOSED AS HAVING END-STAGE RENAL DISEASE RECEIVE THE CARE THEY NEED;

o TO ENCOURAGE PROPER ACCESS TO CARE WHILE MAINTAINING OR IMPROVING THE QUALITY OF THAT CARE;

- TO PROVIDE FOR THE EFFICIENT DELIVERY OF APPROPRIATE CARE BY PHYSICIANS AND FACILITIES; AND

- TO ENCOURAGE SELF-DIALYSIS OR TRANSPLANTATION FOR THE MAXIMUM PRACTICAL NUMBER OF PATIENTS WHO ARE MEDICALLY, SOCIALLY, AND PSYCHOLOGICALLY SUITABLE CANDIDATES FOR SUCH TREATMENTS.

GROWTH OF ESRD PROGRAM

TO PLACE THE OPERATION OF THE PROGRAM IN PERSPECTIVE, I BELIEVE IT WILL BE HELPFUL TO OUTLINE THE GROWTH OF THE PROGRAM SINCE ITS INCEPTION.

FACILITIES

KIDNEY DIALYSIS TREATMENTS ARE MOST FREQUENTLY PROVIDED IN ONE OF TWO SETTINGS: HOSPITAL-BASED FACILITIES OR FREESTANDING FACILITIES. THE NUMBER OF HOSPITAL-BASED FACILITIES HAS REMAINED RELATIVELY STABLE SINCE THE INCEPTION OF THE PROGRAM. AS SHOWN ON CHART I, THERE WERE 536 HOSPITAL-BASED FACILITIES IN 1973 COMPARED TO 654 IN 1981. FREE-STANDING FACILITIES, HOWEVER, HAVE EXPERIENCED A DRAMATIC GROWTH DURING THE

SAME TIME PERIOD. THERE WERE 68 SUCH FACILITIES IN 1973 COMPARED TO 466 IN 1981. YOU CAN SEE THE PRESENT DISTRIBUTION OF THESE FACILITIES ACROSS THE NATION ON THE LARGE "PIN" CHART.

BENEFICIARIES

MY NEXT CHART TRACES THE GROWTH OF THE PROGRAM FROM 1974 (THE FIRST FULL YEAR OF OPERATION) TO 1981. AS THIS CHART SHOWS, IN 1974, THERE WERE 18,412 RENAL BENEFICIARIES. THE NUMBER OF BENEFICIARIES STEADILY INCREASED YEAR-BY-YEAR, WITH AN AVERAGE ANNUAL RATE OF INCREASE OF ABOUT 20 PERCENT. BY THE END OF 1981, THERE WERE MORE THAN 60,000 BENEFICIARIES, ALMOST THREE-AND-ONE-HALF TIMES THE ORIGINAL NUMBER.

I SHOULD POINT OUT THAT THESE MEDICARE BENEFICIARIES ACCOUNT FOR APPROXIMATELY 93 PERCENT OF ALL PATIENTS WITH IRREVERSIBLE KIDNEY FAILURE. THE ESRD PROGRAM REQUIREMENTS FOR MEDICARE ELIGIBILITY ARE QUITE BROAD, AND VIRTUALLY THE ENTIRE POPULATION OF DIALYSIS AND TRANSPLANT PATIENTS IS COVERED UNDER THE PROGRAM.

COST

THIS DRAMATIC INCREASE IN THE GROWTH OF BENEFICIARIES, IS, OF COURSE, ONE OF THE MAJOR FACTORS THAT ACCOUNTS FOR THE SIGNIFICANT INCREASE IN THE COST OF THE RENAL PROGRAM. PROGRAM EXPENDITURES GREW FROM $228.5 MILLION IN 1974, THE FIRST FULL YEAR OF OPERATION, TO ABOUT $1.6 BILLION IN FY 1981.

WE CAN GAIN FURTHER APPRECIATION OF THE HIGH COST OF THE ESRD PROGRAM FROM THE FACT THAT THE RENAL BENEFICIARIES REPRESENT LESS THAN ONE-QUARTER OF ONE PERCENT OF ALL MEDICARE BENEFICIARIES. YET THIS ONE-QUARTER OF ONE PERCENT ACCOUNTS FOR ABOUT TEN PERCENT OF ALL MEDICARE PART B REIMBURSEMENT AND JUST OVER ONE PERCENT OF PART A.

THE CURRENT SYSTEM OF MEDICARE REIMBURSEMENT RULES IS PARTLY TO BLAME FOR THE DRAMATIC INCREASE IN ESRD PROGRAM EXPENDITURES. IF THERE WERE NO CHANGES IN CURRENT REIMBURSEMENT RULES, WE ESTIMATE THAT TOTAL COSTS FOR THE ESRD PROGRAM MAY RISE TO AS MUCH AS $1.8 BILLION IN FY 1982 AND TO ALMOST $2.4

BILLION BY 1984. THE CONGRESS AND THE ADMINISTRATION HAVE BOTH RECOGNIZED THAT CHANGES MUST BE MADE TO RESTRAIN SUCH COST INCREASES. THE 1981 OMNIBUS BUDGET RECONCILIATION ACT'S ESRD PROSPECTIVE REIMBURSEMENT PROVISION AND ITS IMPLEMENTING PROPOSED REGULATION REPRESENT A MAJOR STEP IN ACHIEVING THIS GOAL. BEFORE DISCUSSING THIS REGULATION IN DETAIL, I WOULD LIKE TO QUICKLY REVIEW THE CHARACTERISTICS OF OUR CURRENT REIMBURSEMENT SYSTEM.

CURRENT MEDICARE REIMBURSEMENT RULES

UNDER CURRENT MEDICARE REIMBURSEMENT RULES, HOSPITALS, ON THE ONE HAND, ARE REIMBURSED RETROACTIVELY FOR THEIR REASONABLE COSTS. GENERALLY, THEY ARE REIMBURSED FOR WHATEVER THEY SPEND. THIS METHOD OFFERS LITTLE INCENTIVE TO THE FACILITIES TO MAKE THEIR OPERATIONS MORE EFFICIENT SINCE THEY MAY NOT RETAIN ANY EXCESS OF MEDICARE REVENUES OVER MEDICARE COSTS, EVEN IF THESE COSTS ARE REDUCED THROUGH MORE EFFICIENT OPERATION. FREE-STANDING FACILITIES, ON THE OTHER HAND, ARE REIMBURSED ON THE BASIS OF THEIR REASONABLE CHARGES, UP TO A MAXIMUM PAYMENT SCREEN OF $138 PER TREATMENT. NEARLY ALL FREE-STANDING FACILITIES CLAIM THIS MAXIMUM REASONABLE CHARGE AND ARE PAID AT THE RATE OF $138 PER TREATMENT.

THESE FACILITIES MAY RETAIN THE TOTAL DIFFERENCE BETWEEN THEIR CHARGES AND ACTUAL COSTS.

WITH RESPECT TO IN-FACILITY DIALYSIS, WE HAVE CONDUCTED AUDITS TO DETERMINE HOW OUR REIMBURSEMENT AMOUNTS COMPARED WITH THE ACTUAL COSTS OF PROVIDING DIALYSIS. THESE AUDITS INCLUDED THE COSTS OF DIALYSIS PROVIDED IN BOTH TYPES OF FACILITIES.

AUDITED ESRD COST DATA ANALYZED IN 1981 SHOW THAT THE MEDIAN COST PER IN-FACILITY DIALYSIS WAS $135 FOR HOSPITAL-BASED FACILITIES. THIS COST WAS SOME 25 PERCENT HIGHER THAN THE $108 MEDIAN FOR FREE-STANDING FACILTIES. WE BELIEVE THAT THIS DISPARITY IN COSTS BETWEEN THE TWO TYPES OF FACILITIES REFLECTS THE ABSENCE THAT I MENTIONED OF EFFECTIVE INCENTIVES FOR MAXIMUM EFFICIENCY IN THE COST-BASED HOSPITAL SETTING. OF EQUAL CONCERN TO THE DEPARTMENT, HOWEVER, IS THE FACT THAT DESPITE THE MEDIAN COSTS OF $108 PER TREATMENT, NEARLY ALL FREE-STANDING FACILITIES HAVE CHARGED $138 PER TREATMENT. HENCE, NEITHER THE FEDERAL GOVERNMENT NOR THE ESRD BENEFICIARY POPULATION HAS BENEFITED FULLY FROM THE OPERATING EFFICIENCIES AND LOWER COSTS OF THE FREE-STANDING FACILITIES.

WITH RESPECT TO HOME DIALYSIS, ADDITIONAL AUDIT DATA SHOW MEDIAN COSTS TO BE ABOUT $97 PER TREATMENT. ALTHOUGH HOME DIALYSIS IS BELIEVED TO BE SUITABLE AND APPROPRIATE FOR AS MANY AS 30 TO 40 PERCENT OF ALL ESRD PATIENTS, IT IS ACTUALLY USED FOR ONLY ABOUT 17 PERCENT OF PATIENTS NATIONWIDE.

AS SHOWN ON CHART III, WITHIN THIS NATIONAL AVERAGE THERE ARE WIDE VARIATIONS AMONG GEOGRAPHICAL AREAS. FOR EXAMPLE, THE RATE FOR CALIFORNIA IS ONLY 9.1 PERCENT WHILE THE RATE OF WASHINGTON STATE IS 54.2 PERCENT. HENCE, THE POTENTIAL BENEFITS TO BE GAINED FROM WIDER USE OF THIS LOWER-COST TREATMENT MODALITY HAVE ALSO NOT ACCRUED TO THE ESRD PROGRAM. IN ADDITION TO THE FINANCIAL ADVANTAGES, HOME DIALYSIS PATIENTS CAN LEAD A MORE NORMAL LIFE WITH INCREASED OPPORTUNITIES FOR INDEPENDENCE, REHABILITATION, AND MEANINGFUL EMPLOYMENT.

I FIND IT RATHER DISTURBING THAT AT ONE TIME THE HOME DIALYSIS RATE WAS AS HIGH AS 40 PERCENT. THIS WAS IN 1972, BEFORE THE ESRD PROGRAM WAS INITIATED. THE DECLINE IN THIS RATE TO THE PRESENT 17 PERCENT IS DIRECTLY ATTRIBUTABLE TO DISINCENTIVES TO HOME DIALYSIS THAT WERE INCLUDED IN THE ORIGINAL ESRD LEGISLATION AND ITS IMPLEMENTATION. AS YOU KNOW, SOME

OF THESE DISINCENTIVES WERE REMOVED IN THE 1978 ESRD AMENDMENTS. WITH THE ADDITIONAL INCENTIVES FOR HOME DIALYSIS INCLUDED IN THE 1981 AMENDMENTS AND OUR PROPOSED REGULATION, WE LOOK TO RETURNING TO GREATER LEVELS OF HOME DIALYSIS. ACHIEVING THIS SHIFT ALONE WOULD SUBSTANTIALLY REDUCE THE PROGRAM'S RATE OF COST INCREASES.

AUDITS

THE COST DATA THAT I HAVE BEEN CITING WERE DERIVED FROM AUDITS OF TWO SAMPLES OF FACILITIES. SINCE QUESTIONS HAVE BEEN RAISED ABOUT THESE AUDITS, I WOULD LIKE TO TAKE A FEW MINUTES TO DESCRIBE HOW THEY WERE CONDUCTED. IN ORDER TO SELECT A REPRESENTATIVE SAMPLE OF FACILITIES TO AUDIT, WE DIVIDED ALL OF THE OPERATING FACILITIES INTO FOUR GROUPS (URBAN HOSPITAL, URBAN INDEPENDENT, RURAL HOSPITAL, AND RURAL INDEPENDENT) AND THEN STRATIFIED THESE GROUPS BY TOTAL REPORTED COSTS. FROM THIS ARRAY, WE SELECTED FACILITIES FROM EACH STRATUM (E.G., URBAN INDEPENDENT FACILITIES WITH REPORTED ANNUAL COSTS OF $500,000 OR LESS). THIS STATISTICAL SAMPLING PROCESS LED TO THE SELECTION IN MARCH 1980 OF A STRATIFIED SAMPLE OF 110 FACILITIES FROM 825 NON-FEDERAL

ESRD FACILITIES THAT WERE FURNISHING IN-FACILITY OUTPATIENT DIALYSIS SERVICES AT THAT TIME. THIS INITIAL SAMPLE INCLUDED 70 OF THE HOSPITAL-BASED FACILITIES AND 40 OF THE FREE-STANDING FACILITIES, WHICH AMOUNTED TO 13 PERCENT OF ALL FACILITIES THAT WERE OPERATING.

THE AUDITS ACTUALLY PERFORMED INVOLVED 38 FREE-STANDING FACILITIES AND 67 HOSPITALS. AS I MENTIONED, THESE AUDITS WERE CONDUCTED SO THAT WE COULD ESTIMATE THE ACTUAL COST OF PROVIDING IN-FACILITY DIALYSIS SERVICES IN ACCORDANCE WITH MEDICARE COST-REPORTING PRINCIPLES. THESE COST ESTIMATES WERE TO BE USED FOR THE PURPOSE OF ESTABLISHING AN INCENTIVE REIMBURSEMENT METHODOLOGY AND PAYMENT RATES FOR FACILITY DIALYSIS, AS MANDATED BY THE END-STAGE RENAL DISEASE AMENDMENTS OF 1978.

RECONCILIATION ACT OF 1981

BEFORE THE DEPARTMENT COULD IMPLEMENT SUCH AN INCENTIVE REIMBURSEMENT SYSTEM, THE OMNIBUS BUDGET RECONCILIATION ACT OF 1981 WAS ENACTED. AS YOU KNOW, THE 1981 ACT MANDATED THAT PAYMENTS FOR ESRD SERVICES DIFFERENTIATE BETWEEN HOSPITAL-

BASED AND FREE-STANDING TYPES OF FACILITIES AND PROVIDE GREATER INCENTIVES FOR HOME DIALYSIS. THIS WAS TO BE ACHIEVED BY A COMPOSITE RATE THAT WOULD APPLY TO BOTH HOME DIALYSIS AND FACILITY TREATMENTS OR BY A MORE EFFICIENT ALTERNATIVE. HOWEVER, BECAUSE THE FIRST GROUP OF AUDITS HAD INCLUDED ONLY THE COSTS OF IN-FACILITY DIALYSIS, IT WAS NECESSARY TO CONDUCT A SECOND GROUP OF AUDITS TO IDENTIFY THE COSTS OF HOME DIALYSIS. WITH THE COSTS OF HOME DIALYSIS IDENTIFIED, WE WOULD THEN BE ABLE TO INCLUDE THOSE COSTS IN THE COMPOSITE RATE AS REQUIRED BY THE 1981 ACT. THESE AUDITS WERE CONDUCTED LAST FALL IN COOPERATION WITH THE OFFICE OF THE INSPECTOR GENERAL. THE AUDIT SAMPLE CONSISTED OF 25 OF THE LARGEST HOME DIALYSIS PROGRAMS IN THE COUNTRY, REPRESENTING THE EXPERIENCE OF 30 PERCENT OF ALL HOME DIALYSIS PATIENTS.

I SHOULD NOTE THAT BECAUSE OF THE SEVERE TIME RESTRAINTS IMPOSED BY THE LAW, IT WAS IMPOSSIBLE TO DETERMINE IF ALL OF THE REPORTED COSTS WERE REASONABLE AND ALLOWABLE UNDER THE MEDICARE REIMBURSEMENT PRINCIPLES. HOWEVER, WE BELIEVE THAT OUR AGGREGATE COST REVIEW RESULTS REASONABLY REPRESENT THE MEDIAN COSTS OF FURNISHING HOME DIALYSIS. WE WILL, OF COURSE, REVIEW ALL REPORTED COSTS ANNUALLY TO DETERMINE WHAT ADJUSTMENTS ARE NEEDED IN THE RATES.

NOW, I WOULD LIKE TO DISCUSS FURTHER THE PROSPECTIVE RATE REIMBURSEMENT SYSTEM PROVIDED UNDER THE 1981 RECONCILIATION ACT. THE STATUTE SPECIFIES A PREFERENCE FOR SEPARATE COMPOSITE RATES -- I.E., ONE COMPOSITE RATE FOR HOSPITALS AND ANOTHER FOR FREE-STANDING FACILITIES. THESE RATES ARE TO TAKE INTO ACCOUNT THE COSTS OF IN-FACILITY AND AT-HOME DIALYSIS AND THE RESPECTIVE PROPORTIONS OF PATIENTS DIALYZING IN EACH LOCATION. THE COMPOSITE RATES WOULD THEN BE PAID FOR EACH TREATMENT, WHETHER RENDERED AT A FACILITY OR AT HOME.

COMPOSITE RATES ARE EXPECTED TO YIELD A SUBSTANTIAL FINANCIAL INCENTIVE TO A FACILITY FOR EACH PATIENT WHO IS DIALYZED AT HOME AND A LESSER MARGIN FOR THOSE TREATED IN THE FACILITY. SINCE WE WILL BE PAYING THE SAME RATE FOR DIALYSIS PERFORMED IN THE HOME AND DIALYSIS PERFORMED IN A FACILITY -- AND HOME DIALYSIS IS LESS COSTLY ON THE AVERAGE -- ALL PROVIDERS WILL HAVE AN INCENTIVE TO SHIFT PATIENTS TO HOME DIALYSIS WHERE PHYSICIANS DETERMINE THAT HOME DIALYSIS IS SUITABLE.

DESCRIPTION OF METHODOLOGY

CHART IV SUMMARIZES THE RATE CALCULATION. THE ACTUAL PAYMENT METHODOLOGY THAT WE EMPLOYED USES AS A DEPARTURE POINT THE MEDIAN COSTS OF HOME DIALYSIS ($97) AND OF FACILITY DIALYSIS ($126) FOR ALL FACILITIES AUDITED. THESE COSTS WERE THEN WEIGHTED BY THE PROPORTIONS OF PATIENTS DIALYZING IN EACH LOCATION (I.E., OF HOSPITAL PATIENTS, 23.5 PERCENT DIALYZE AT HOME AND 76.5 PERCENT IN FACILITY; OF INDEPENDENT ESRD PATIENTS, 10.5 PERCENT ARE AT HOME AND 89.5 PERCENT ARE IN FACILITY).

THE DEPARTMENT THEN DETERMINED THAT THE RECONCILIATION ACT REQUIREMENT FOR DIFFERENTIATION BETWEEN HOSPITAL AND INDEPENDENT FACILITIES SHOULD FURTHER BE CARRIED OUT BY ADJUSTING THE HOSPITAL RATE TO ACCOUNT ONLY FOR LEGITIMATE HIGHER COSTS INCURRED BY HOSPITALS AS A GROUP. THE HOSPITAL RATE WAS THEREFORE RAISED BY $2.10 TO ACCOUNT FOR AN APPARENT EXCESS (OVER THE MEDIAN FOR ALL FACILITIES) IN HOSPITAL OVERHEAD COSTS RESULTING FROM MEDICARE HOSPITAL ACCOUNTING REQUIREMENTS. NO ADJUSTMENT WAS MADE TO RECOGNIZE THE HOSPITAL'S GENERALLY HIGHER COSTS OF LABOR AND SUPPLIES SINCE WE HAVE NO EVIDENCE THAT SUCH EXCESS COSTS ARE JUSTIFIABLE FOR HOSPITALS AS A CLASS OF PROVIDERS.

ONE FURTHER ADJUSTMENT WAS MADE. A FIVE PERCENT FACTOR WAS ADDED TO THE HOSPITAL RATE TO ACCOUNT FOR THE POSSIBILITY THAT THE METHODOLOGY USED MAY HAVE FAILED TO RECOGNIZE FULLY THE LEGITIMATE COSTS OF HOSPITALS OR POSSIBLE SHORTCOMINGS IN THE AUDITED DATA.

ANOTHER FACTOR USED IN SETTING THE RATE IS THE DIRECTIVE IN THE CONFERENCE COMMITTEE REPORT ON THE 1981 ACT THAT THE RATES PAID TO INDIVIDUAL FACILITIES WOULD VARY WITH LOCAL LABOR COSTS. WE FOUND THE MOST RELIABLE WAGE DATA AVAILABLE TO BE THAT COMPILED BY THE BUREAU OF LABOR STANDARDS (BLS) AND USED FOR THE MEDICARE HOSPITAL COSTS LIMITS. FROM THE BLS DATA, WE DEVELOPED AREA WAGE INDEXES THAT RELECT THE RELATIONSHIP OF LOCAL WAGE LEVELS TO THE NATIONAL AVERAGE.

AFTER TAKING ALL OF THESE FACTORS INTO ACCOUNT, THE COMPUTATION OF THE PROSPECTIVE REIMBURSEMENT RATE YIELDS AN AVERAGE PAYMENT PER TREATMENT OF $132 FOR HOSPITAL-BASED FACILITIES (RANGING FROM A LOW OF $114 TO A HIGH OF $148). THE AVERAGE RATE OF INDEPENDENT FACILITIES WOULD BE $128 (RANGING FROM A LOW OF $109 TO A HIGH OF $143). AS I STATED EARLIER, THE SAME RATE WOULD BE PAID FOR BOTH HOME AND IN-FACILITY DIALYSIS. MOREOVER, IT IS A PROSPECTIVE RATE, AND UNLIKE THE PROCESS OF THE PRESENT RETROACTIVE COST-REIMBURSEMENT METHOD, THERE WOULD BE NO COST SETTLEMENT AT THE END OF THE PERIOD.

EXCEPTIONS

THE PROPOSED REGULATION ALSO PROVIDES FOR AN EXCEPTIONS PROCESS THAT WOULD ALLOW THE PAYMENT OF HIGHER RATES FOR FACILITIES WITH JUSTIFIABLY HIGHER COSTS. WE PROPOSE TO CONSIDER EXCEPTIONS FOR A FACILITY THAT IS ABLE TO PROVIDE CONVINCING EVIDENCE THAT IT HAS EXCESSIVE COSTS THAT ARE ATTRIBUTABLE TO ONE OF THE FOLLOWING CONDITIONS:

- ATYPICAL PATIENT MIX, FOR EXAMPLE, A PEDIATRIC DIALYSIS UNIT WITH UNUSUAL STAFFING REQUIREMENTS;

- ISOLATED ESSENTIAL FACILTIES;

- EXTRAORDINARY CIRCUMSTANCES (FLOODS, FIRES, ETC.); AND

- EDUCATIONAL COSTS, IF COSTS ARE DIRECTLY ATTRIBUTABLE TO APPROVED EDUCATION PROGRAMS THAT INVOLVE OUTPATIENT DIALYSIS SERVICES.

ANY FACILITY WHOSE EXCEPTION REQUEST IS DENIED COULD APPEAL TO THE INTERMEDIARY, AND, SUBSEQUENTLY, IF THE AMOUNT IN DISPUTE IS $10,000 OR MORE, TO THE PROVIDER REIMBURSEMENT REVIEW BOARD ESTABLISHED UNDER THE MEDICARE LAW. THE LAW ALSO PROVIDES FOR FURTHER RIGHT OF APPEAL TO THE U.S. DISTRICT COURT.

PHYSICIAN REIMBURSEMENT

WE ARE ALSO PROPOSING TO REVISE PHYSICIAN REIMBURSEMENT METHODS TO PROMOTE EFFICIENT DELIVERY OF DIALYSIS SERVICES AND PROVIDE INCENTIVES FOR HOME DIALYSIS. CURRENTLY, THERE ARE TWO WAYS THAT PHYSICIANS ARE PAID FOR THEIR ESRD SERVICES -- THE INITIAL METHOD (IM) AND THE ALTERNATIVE REIMBURSEMENT METHOD (ARM).

UNDER THE INITIAL METHOD, REIMBURSEMENT FOR SUPERVISORY PATIENT CARE SERVICES IS MADE TO A FACILITY AS PART OF THE FACILITY'S REIMBURSEMENT RATE. ALL SERVICES FURNISHED

TO HOME DIALYSIS PATIENTS ARE BILLED ON AN INDIVIDUAL FEE-FOR-SERVICE BASIS. THE PHYSICIAN MUST PHYSICALLY SEE THE PATIENT IN ORDER TO BE PAID, SINCE NO ALLOWANCE IS MADE FOR GENERAL SUPERVISION OF HOME PATIENTS.

UNDER THE ALTERNATIVE REIMBURSEMENT METHOD, PHYSICIANS ARE PAID A COMPREHENSIVE MONTHLY FEE (APPROXIMATELY $220 PER PATIENT PER MONTH) FOR ALMOST ALL OF THE ESRD SERVICES FURNISHED TO PATIENTS DIALYZED IN FACILITIES. BECAUSE THERE IS ONE MONTHLY BILL, THERE IS MORE CONTROL OVER THE OVERALL REIMBURSEMENT PHYSICIANS RECEIVE. PHYSICIANS ARE ALSO PAID ON THE BASIS OF A LOWER MONTHLY FEE FOR SUPERVISING ALL OF THEIR HOME DIALYSIS PATIENTS. ON THE AVERAGE, THIS FEE IS $154 PER PATIENT PER MONTH.

THE CURRENT REIMBURSEMENT METHODS PROVIDE AN ECONOMIC INCENTIVE FOR PHYSICIANS TO TREAT DIALYSIS PATIENTS IN A FACILITY, RATHER THAN AT HOME. THIS IS, OF COURSE, INCONSISTENT WITH THE STATUTORY GOAL TO STIMULATE HOME DIALYSIS. I BELIEVE THAT WE MUST DEAL WITH PHYSICIAN INCENTIVES AS WELL AS FACILITY INCENTIVES BECAUSE THE PHYSICIAN IS THE PRIMARY DECISION-MAKER ON HOW TREATMENT IS TO BE FURNISHED.

WE HAVE PROPOSED TO DO THIS BY ELIMINATING THE INITIAL METHOD AND ESTABLISHING EQUAL PHYSICIAN CAPITATION MONTHLY PAYMENTS FOR HOME DIALYSIS AND IN-FACILITY DIALYSIS. THIS WILL MEAN TOTAL FEDERAL NEUTRALITY AS TO WHERE PATIENTS ARE PLACED AND THE SPECIFIC MODE OF TREATMENT PRESCRIBED. IN THIS WAY, WE WOULD NOT, AS UNDER CURRENT PRACTICES, GIVE PHYSICIANS A FINANCIAL INCENTIVE FOR TREATING THEIR PATIENTS IN THE FACILITY RATHER THAN AT HOME BY PAYING THEM MORE FOR IN-FACILITY TREATMENT. WE ARE PROPOSING IN THE NEW REGULATION AN AVERAGE PAYMENT OF $184 PER MONTH FOR BOTH HOME AND IN-FACILITY PATIENTS. THIS PAYMENT IS BASED ON A COMPOSITE WEIGHTED FORMULA TO ACCOUNT FOR THE PROPORTION OF PATIENTS CURRENTLY DIALYZING AT HOME.

HOME DIALYSIS EQUIPMENT

ANOTHER REVISION THAT WE PROPOSE TO MAKE AFFECTS REIMBURSEMENT FOR CERTAIN HOME DIALYSIS EQUIPMENT. THE ESRD PROGRAM IS NOW PERMITTED TO REIMBURSE A QUALIFIED FACILITY OR STATE ESRD PROGRAM FOR THE FULL COST OF HOME DIALYSIS EQUIPMENT, INCLUDING INSTALLATION, MAINTENANCE, AND REPAIR. THIS OPTION WAS PROVIDED TO ENCOURAGE HOME DIALYSIS BY RELIEVING

THE COINSURANCE BURDEN ON THE BENEFICIARIES, AND TO AVOID HIGH EQUIPMENT RENTAL PAYMENTS, WHICH HAVE SOMETIMES EXCEEDED THE PURCHASE PRICE.

WE HAVE PROPOSED DISCONTINUING THIS OPTION WHEN THE PROSPECTIVE SYSTEM BEGINS OPERATION. THERE WOULD BE SEVERE DIFFICULTIES IF WE CONTINUED TO ADMINISTER THE REIMBURSEMENT IN THIS WAY, BECAUSE THE COMPOSITE RATE WOULD FREQUENTLY HAVE TO BE ADJUSTED TO ACCOUNT FOR THE FACT THAT THE COSTS OF EQUIPMENT AND RELATED SERVICES WOULD ALREADY HAVE BEEN REIMBURSED BY THE PROGRAM. ELIMINATING THIS OPTION WOULD MAKE THE PROSPECTIVE SYSTEM SIMPLER AND MORE COMPREHENSIVE, AND REDUCE THE RECORDKEEPING BURDEN FOR THE FACILITIES. HOWEVER, ANY EQUIPMENT PURCHASED BEFORE THE EFFECTIVE DATE OF THE PROSPECTIVE SYSTEM WOULD, UNDER OUR PROPOSAL, BE HANDLED UNDER THE TERMS OF THE ESTABLISHED AGREEMENTS, WITH APPROPRIATE ADJUSTMENT IN THE RATES OF THE PARTICULAR FACILITIES.

THIS COMPLETES MY SUMMARY OF THE MAJOR REIMBURSEMENT CHANGES WHICH HAVE BEEN PROPOSED UNDER THE PROSPECTIVE RATE REGULATIONS.

COMMENTS ON PROPOSED REGULATIONS

AS YOU KNOW, THE COMMENT PERIOD ON THE PROPOSED REGULATION ENDED APRIL 13, 1982. WE ARE NOW IN THE PROCESS OF REVIEWING AND ANALYZING THE MORE THAN 1.800 COMMENTS WE HAVE RECEIVED REGARDING THE PROPOSED REGULATION. WE APPRECIATE HAVING RECEIVED FROM THIS COMMITTEE YOUR LETTER OF MARCH 30 EXPRESSING PARTICULAR CONCERNS AND COMMENTS ON OUR PROPOSAL. I WOULD LIKE TO TAKE A FEW MINUTES TO SHARE WITH YOU THE MAJOR CONCERNS THAT ARE EXPRESSED IN THE COMMENTS WHICH WE HAVE ANALYZED AND OUR PRELIMINARY REACTIONS TO THEM.

REDUCTION IN ACCESS AND QUALITY OF CARE

MOST OF THE COMMENTS EXPRESSED THE CONCERN THAT ACCESS TO CARE AND QUALITY OF CARE WILL BE ADVERSELY AFFECTED BY THE LOWER RATES. SOME COMMENTERS BELIEVE THAT FACILITIES WILL CLOSE AND THAT OTHER FACILITIES WHICH CONTINUE TO OPERATE WILL REDUCE THEIR STAFFS. THEREFORE, QUALITY OF CARE WILL SUFFER.

OF COURSE, WE CANNOT GUARANTEE THAT NO FACILITIES WILL CLOSE. HOWEVER, OUR EXCEPTIONS PROCESS WILL BE AVAILABLE TO DEAL WITH PROBLEMS ENCOUNTERED BY ISOLATED FACILITIES. IN ADDITION, WE ANTICIPATE THAT "FACILITY" MERGERS MIGHT OCCUR WHICH WOULD CONTINUE EFFICIENT AND HIGH QUALITY DELIVERY OF CARE. OUR UNDERSTANDING OF THE ESRD INDUSTRY LEADS US TO BELIEVE THAT OUR PROPOSAL WOULD NOT RESULT IN A DISRUPTION OF SERVICES TO BENEFICIARIES.

WITH RESPECT TO THE CONCERNS ABOUT REDUCED QUALITY OF SERVICES, WE WILL MAINTAIN OUR FACILITY SURVEYS OF THE HEALTH AND SAFETY STANDARDS AND OUR MONITORING OF THE STATISTICAL INDICATORS OF QUALITY--AND, NATURALLY, ANY PATIENT COMPLAINTS--TO ASSURE THAT QUALITY OF CARE IS NOT REDUCED BELOW PROGRAM STANDARDS. IF PROBLEMS DO OCCUR, WE WOULD ANTICIPATE WORKING WITH FACILITIES ON IDENTIFIED PROBLEMS. HOWEVER, WE WILL NOT ALLOW A FACILITY TO CONTINUE TO PARTICIPATE IF IT DOES NOT MEET THE QUALITY OF CARE REQUIREMENTS THAT THE PROGRAM HAS ESTABLISHED.

I BELIEVE THAT THOSE WHO EXPRESSED THESE CONCERNS DO NOT FULLY UNDERSTAND THE PROSPECTIVE RATE METHODOLOGY. THERE IS NOT A CLEAR UNDERSTANDING THAT WE INTEND TO PAY THE FACILITIES THE COMPOSITE RATE FOR ALL OF THE HOME TREATMENTS

THAT THEY SUPERVISE AND THAT THIS WILL AFFECT THEIR TOTAL REIMBURSEMENT LEVEL IN A POSITIVE FASHION. IN THIS ENTIRE RATE DETERMINATION PROCESS, WE HAVE SOUGHT TO BALANCE FISCAL PRUDENCE WITH ASSURANCE OF PATIENT ACCESS AND MAINTENANCE OF QUALITY SERVICES. I WILL ASSURE THAT THE FINAL RATES REFLECT A REALISTIC BALANCE.

RURAL FACILITY RATES

WE RECEIVED A NUMBER OF COMMENTS CONCERNING THE WAGE INDEX COMPONENT OF THE COMPOSITE RATE, INDICATING THAT THE PROPOSAL WOULD RESULT IN LOWER RATES WHICH ARE UNFAIR TO RURAL FACILITIES. IN ESTABLISHING THE WAGE INDEX--WHICH TAKES INTO ACCOUNT THE FACT THAT FACILITY LABOR COSTS ARE GENERALLY LOWER IN RURAL AREAS THAN IN URBAN AREAS--WE HAVE TRIED TO BE RESPONSIVE TO CONGRESSIONAL INTENT. HOWEVER, WE ARE CAREFULLY CONSIDERING THESE COMMENTS TO DETERMINE IF ANY ADJUSTMENT IS WARRANTED.

HOSPITAL RATES

WE RECEIVED A NUMBER OF COMMENTS SUGGESTING THAT THE PROPOSED $4 DIFFERENTIAL BETWEEN THE AVERAGE RATES FOR HOSPITAL-BASED FACILITIES AND FOR INDEPENDENT FACILITIES SHOULD BE INCREASED. THESE COMMENTERS CLAIMED THAT THE HOSPITAL

RATE SHOULD BE HIGHER BECAUSE HOSPITAL PATIENTS REQUIRE MORE CARE THAN THOSE TREATED BY THE INDEPENDENT FACILITIES. BEFORE WE DETERMINED THE RATES, WE EXAMINED THE EXISTING DATA TO ASCERTAIN IF THERE WERE ANY DIFFERENCES IN CASE-MIX BETWEEN THE PATIENTS DIALYZED IN THE TWO TYPES OF FACILITIES. WE FOUND NO DIFFERENCE. HOWEVER, BECAUSE THIS IS SUCH AN IMPORTANT ISSUE, WE ARE REVIEWING THE DATA CAREFULLY. WE EXPECT THAT THIS REVIEW WILL BE COMPLETED SHORTLY SO THAT WE CAN DETERMINE WHETHER ANY CASE-MIX DIFFERENCE EXISTS THAT WOULD WARRANT A CHANGE IN THE RATES OR ADJUSTMENT IN THE PROPOSED METHODOLOGY.

HOME DIALYSIS

A NUMBER OF COMMENTERS EXPRESSED THE CONCERN THAT THE NEW SYSTEM WILL PRESSURE PATIENTS WHO ARE NOT APPROPRIATE CANDIDATES FOR THIS TREATMENT TO BECOME HOME DIALYSIS PATIENTS. I WANT TO EMPHASIZE THAT WHILE WE WISH TO ENCOURAGE THE INCREASED USE OF HOME DIALYSIS, THESE PATIENTS MUST BE FOUND BY THEIR PHYSICIANS TO BE MEDICALLY AND PSYCHOLOGICALLY SUITABLE FOR HOME DIALYSIS.

IN ADDITION, FOR HEMO-DIALYSIS PERFORMED IN THE HOME, THE PHYSICIAN MUST ALSO DETERMINE THAT THE PATIENT HAS A RELIABLE DIALYSIS PARTNER WILLING TO ASSIST HIM WITH THE TREATMENTS. MOREOVER, THE HOME MUST HAVE SUFFICIENT ROOM AND OTHER FEATURES TO ACCOMMODATE THE DIALYSIS EQUIPMENT.

I SHOULD ALSO POINT OUT THAT BEFORE HOME DIALYSIS IS INITIATED, BOTH THE PATIENT AND THE DIALYSIS PARTNER RECEIVE A PERIOD OF THOROUGH TRAINING ON CONDUCTING THE DIALYSIS PROCESS. IF IT IS FOUND DURING THIS PERIOD THAT HOME DIALYSIS IS NOT FEASIBLE, THE PATIENT IS REFERRED BACK FOR IN-FACILITY DIALYSIS.

AS I SAID EARLIER, WE ARE ANALYZING THE COMMENTS WE HAVE RECEIVED TO DETERMINE WHETHER THEY POINT TO A NEED TO MAKE CHANGES IN THE REGULATION. AS SOON AS THIS REVIEW IS COMPLETED, WE WILL MOVE TOWARD PUBLISHING THE FINAL REGULATION. WE KNOW THAT CONCERNS HAVE BEEN EXPRESSED ABOUT THE NEED FOR A TRANSITION PERIOD BEFORE PUTTING THE NEW RATES INTO EFFECT. THE ORIGINAL LEGISLATION CALLING FOR PROSPECTIVE RATE REIMBURSEMENT WAS ENACTED IN 1978. THE 1981 LEGISLATION REAFFIRMED THE REQUIREMENT FOR THE CHANGE IN THE REIMBURSEMENT METHOD. THE SECRETARY ANNOUNCED THE PROPOSED PAYMENT LEVELS IN NOVEMBER 1981. ALTHOUGH WE BELIEVE THAT THE FACILITIES

HAVE HAD CONSIDERABLE TIME TO PLAN FOR THE CHANGE FROM THE PRESENT REIMBURSEMENT SYSTEM TO THE RATE METHOD, WE WILL CONTINUE TO BE SENSITIVE TO THIS PARTICULAR CONCERN.

IN CLOSING, MR. CHAIRMAN, WE BELIEVE THAT THE PROPOSED REIMBURSEMENT SYSTEM MEETS THE STATUTORY REQUIREMENTS THAT ESRD PAYMENT RATES BE PROSPECTIVELY DETERMINED, COMPOSITE IN NATURE, AND PROVIDE INCENTIVES FOR GREATER USE OF HOME DIALYSIS. THE METHODOLOGY IS EQUITABLE IN CONSIDERING THE COSTS OF ALL FACILITIES. IT REWARDS EFFICIENCY BY ENCOURAGING GREATER USE OF LOWER-COST HOME DIALYSIS AND PERMITTING FACILITIES TO RETAIN THE DIFFERENCE BETWEEN THEIR COSTS AND THEIR PAYMENT RATES, AND IT PROVIDES FOR EXCEPTIONS FOR FACILITIES THAT CAN DEMONSTRATE UNUSUAL CIRCUMSTANCES. IN OUR VIEW, IT SHOULD BENEFIT ALL PARTIES CONCERNED.

- THE FEDERAL GOVERNMENT WILL BENEFIT THROUGH LOWER EXPENDITURES;

- FACILITIES WILL BENEFIT THROUGH THE POTENTIAL FOR ADDITIONAL PROFITS THAT WILL RESULT FROM MORE EFFICIENT OPERATIONS AND INCREASED USE OF HOME DIALYSIS; AND

- PATIENTS WILL BENEFIT BY HAVING MORE OPPORTUNITIES FOR DIALYSIS AT HOME WHEN THEIR PHYSICIANS DETERMINE THAT HOME DIALYSIS IS APPROPRIATE.

MR. CHAIRMAN, I WANT TO REITERATE OUR COMMITMENT TO A CAREFUL REVIEW AND ANALYSIS OF THE COMMENTS RECEIVED ON THE PROPOSED REGULATION. THIS CONCLUDES MY PREPARED TESTIMONY. I WILL BE HAPPY TO ANSWER ANY QUESTIONS WHICH YOU MAY HAVE.

Chairman RANGEL. Thank you, Doctor.

You briefly touched on the comments that you received. Were those targeted in that area, the hospitals' questions of different services? That is being studied. How about in the area of pediatrics and the different types of services required for the children?

Ms. DAVIS. We will, obviously, look at that. However, there are roughly 15 pediatric hospitals in the country. We recognize the fact that a pediatric hospital might indeed need an adjustment factor, and I think in our NPRM we clearly identified that as an exception that could justify a higher rate atypical patient mix, and we used the pediatric hospital as one of the examples. We believe that rather than identify a separate rate structure for 15 hospitals, it would be more appropriate for us to simply recognize that they would be those most apt to come in for a rate adjustment through the exception process.

Chairman RANGEL. You are new to the bureaucracy. Are you saying that we can give some type of political assurances that the administration recognizes that there are higher costs of providing services for kids receiving dialysis, and that the regulations may not spell it out but you were thinking about that type of problem?

Ms. DAVIS. We are clearly saying that any institution that can demonstrate that it has an atypical mix and needs more staffing to care for those patients we would take into consideration.

Chairman RANGEL. Doctor——

Ms. DAVIS. May I finish, Mr. Chairman? We have in the past recognized that a number of those 15 pediatric facilities have been ones who have filed for exceptions, and we would anticipate that if they felt they could not live within the current rate, they would again file for that exception.

Chairman RANGEL. Doctor, was any information given to you that would allow anyone to believe that it does cost more to give medical services to children who have kidney failure than it does for older persons? Is there any reason to believe it?

Ms. DAVIS. We do not have data anyone has submitted specifically to that unless it has come in during the comment period. That, of course, is the purpose of the comment period, and we have not had the time since the comment period just closed to analyze those. I do not have in my overall analysis, which has been very brief, any indication as to whether all of the pediatric facilities commented or not.

Chairman RANGEL. All right.

I have asked them to provide me with the information because I do not have it either, and I will see that it is presented to the proper person so that an evaluation can be made as to whether a separate case could be made for the pediatric treatment. I do not know whether it could. A lot of us thought they had made a case.

Mr. STREIMER. Mr. Rangel, historically the pediatric facilities have come in for exceptions. We are and have been historically impressed that pediatric dialysis requires more staffing than does the dialysis of older people, and we fully intend to accommodate that in the exception process.

Chairman RANGEL. We were just impressed with the testimony and wanted to make certain you would review it.

Doctor, you had indicated that some of the information you were working on was dated. How dated?

Ms. DAVIS. A great deal of it was 1979 data, although the home dialysis data was completed in the summer of 1981.

Chairman RANGEL. Do you have any idea how much savings is projected if this regulation as proposed would go into effect?

Ms. DAVIS. About $120 million for fiscal year 1983.

Chairman RANGEL. I have just been advised that the projected deficit for fiscal 1983 will be $175 billion.

Ms. DAVIS. I have not heard that figure.

Chairman RANGEL. Well, you will hear it this afternoon. [General laughter.]

Those people who are talking have not agreed on much, but I think they agreed on that.

My question is: Since you cannot tell with any degree of accurcy how many of these centers would close, should be closed, should never have been in business at all, and we cannot really give assurances to some of the patients that we have enough personnel to make certain that if one of these places closed they would be able to continue to receive dialysis, and since no matter how much we did and how good the data, we will never be able to give those kinds of assurances, would we not both feel a lot better if we had more up-to-date data that would be more accurate and that the general public knew we were doing the best we could, and if mistakes were made after we had the best possible data in reaching a decision, could that be discussed?

Ms. DAVIS. I would be happy to discuss that. Let me discuss two different factors relating to it. One is, since we announced these new rates, I find it very interesting that we have had over 50 requests for approval for new facilities coming on board. So, obviously a number of hospitals and independent facilities believe there must still be an ability to live comfortably within those rates or they would not be requesting an approval as a new facility.

Chairman RANGEL. That is something we did not know.

Let's say this: With that information, is it at all possible that we can give assurances to patients that because we expect new facilities to be opening and to be more competitive, what can we say to the patient who has been informed by the providers that they are closing?

Now, you are saying let them close; someone else will be there. What can we tell the patient who is really concerned with whether or not he or she lives or dies? How do we handle that?

Ms. **Davis**. We handle that by reassuring the individual patient that where there is a sole provider in a community, we have clearly indicated that would be taken care of by the exceptions process. We cannot right now, even with the current rates, assure that no facility will close. A facility may make a decision to close for a number of reasons.

Chairman **Rangel**. Doctor, I know we cannot, and I am not asking you to do it. I am not asking that Members of Congress get off the hook. All I am saying is you and I know that many patients without good cause have reason to believe that reduction in reimbursement could possibly mean the end of their lives.

Ms. **Davis**. I agree, Mr. Chairman. I am afraid patients have been unduly frightened in this whole procedure. I am aware of that myself. I have to call into question some educational information.

Chairman **Rangel**. Well, they claimed it was the Federal Register, and you and I know there was not information in there specifically.

Ms. **Davis**. I must confess I did not realize there was such a large readership of the Federal Register.

Chairman **Rangel**. When you have to read it in order to get dialysis, it increases circulation. [General laughter.]

I hope you recognize that this means we, as partners in government, have a higher responsibility to assure those who may have been miseducated that we are going to walk that extra mile to make certain that they are sure that they will be able to receive services.

Ms. **Davis**. We have the full intention of doing that.

Chairman **Rangel**. Well, I am not saying that you and I know how to do it, but the testimony indicates that you are concerned and we are concerned and the administration is concerned. I would like to find some way of making certain that the public knows about this concern. I hope we can do this before we reach the point where we have a final publication.

Ms. **Davis**. Mr. Chairman, as a former nurse who is familiar with the end-stage renal disease program, and with patients who have this affliction, I believe I have a great deal of compassion for this. I do not intend to see the program aborted in any way. However, we are walking a fine line between the guarantee of accessibility and prudence in fiscal management. We believe we have reached the right conclusion because there are a number of people on each side. We have the Inspector General and the GAO telling us our rates are too high and a number of others telling us they are too low. Again, I go back to saying we used the best data we could. Yes, it is somewhat aged, but we believe we have taken factors into consideration on that. We have also developed a new cost reporting form, and we have asked for sanctions so that we can get all facilities to report on that form. Next year we will take a look at the data we have, and if it is necessary, we will adjust the rates then.

But I will also point out there is an exception process, and we can and will utilize it this year.

Chairman Rangel. All right. I hope we can spell out something in the exception process that may give it the real appearance of being a transition. I think you are saying the exception process gives you flexibility in case you have made a mistake, and I wish we could find some kind of language that would assure people they are covered, the pediatric people, patients who have other types of problems.

I do not know the solution, but I am satisfied——

Ms. Davis. Mr. Chairman, under our current rate of $138 for the hospitals, we have only one-third asking for exceptions now. So, I think it indicates clearly that two-thirds feel they can live within the rate.

Chairman Rangel. The people who testified, when I asked why was there so much concern about the reading of the Federal Register, pointed out that the Federal Register indicated that the regs would under-reimburse 46 percent of the hospital facilities and 28 percent of all nonhospital facilities at a rate below the current cost for in-facility dialysis.

Was that included in the Federal Register?

Mr. Streimer. Yes; Mr. Rangel, and that statement was also characterized as being the effect of the rate if no facilities took any action to either become more efficient or to send people home, or did not have people home at the time.

To show the committee an example: If for instance a hospital with an average composite rate of $132 did indeed send 24 percent of their patients home, their effective rate of reimbursement would be over $143. For an independent facility with an average rate of $128, if they were to send 11 percent of their patients home, their effective reimbursement would be approximately $132. It is difficult to gauge in the individual situation what the exact effect would be on each facility because the amount of people who go home currently and in the future is an unknown quantity.

Chairman Rangel. I feel so inadequate to debate this that these people will be going home because of a manipulation of reimbursement. Really, it is an indictment of the medical profession that they are not encouraging people to get the best type of care if, in fact, they reach the decision that home care is what they should have.

Maybe Mr. Martin would be able to debate that.

Mr. Martin. Mr. Chairman, I have questions along another line.

Chairman Rangel. Sure.

Mr. Martin. Shall I ask them?

Chairman Rangel. Yes.

Mr. Martin. Thank you very much, Mr. Chairman.

Dr. Davis, as I follow your chart, there are about 666 hospitals with operating dialysis centers, and you said a moment ago only that about a third of them filed for exceptions? So roughly about 200 or so, which means the other two-thirds are able to operate below the cost of that screen?

What do they get paid? Do they get paid less than that $138, or do they get paid $138?

Mr. Streimer. The hospital facility reimbursement is settled at the end of the year based on their actual costs. So if their actual cost is less than $138, they get their actual cost. If their actual costs come in right at $138, that is what they would get.

Mr. **Martin**. What about the free-standing facilities? Do they file a cost lower than $138 or do they take $138? Do any of them file for an exception?

Mr. **Streimer**. Very few.

Mr. **Martin**. So all of them take $138 regardless of where they are in the country?

Mr. **Streimer**. That is correct.

Mr. **Martin**. We have had earlier discussions of why their costs might be different. But at least one effect of reducing the screening level is that if any of them are actually incurring costs of more than $138, they would have to file an exception, would they not?

Mr. **Streimer**. They would either have to file for an exception, become more efficient, or send more people home.

Mr. **Martin**. The numbers you have chosen, the new screen is about $132 for hospitals plus or minus $16 or so to allow for wage differentials around the country. Was that chosen as the median of all of them? In other words, do you now expect that half of the hospitals will be filing for exceptions? If it is the median, it will strike in about the middle, right?

Mr. **Streimer**. It is somewhat higher than the median because of the rate methodology, which is where we get the estimate of 46 percent.

Mr. **Martin**. By "somewhat" do you mean slightly higher than the median?

Mr. **Streimer**. That is correct.

Mr. **Martin**. So you would expect that almost half of the hospitals will file, and if their complaint that you have not made allowance for inflation factors is correct, you may have more than half of them filing.

Mr. **Streimer**. What I would really expect is that the majority of the hospitals in that group would take some action to become more efficient. I think it is very important to go back to a comment that was made this morning, where several of the hospital representatives noted that it has actually been, historically, in the hospitals' interest to shift as much cost as possible to the outpatient dialysis department, because the Federal Government reimbursed more money in that department.

We pay on average 90 percent of the cost in the dialysis department, whereas in any other department in the hospital we pay on average 30 percent. So for instance, the George Washington Hospital has $12 per treatment for their educational programs in the hospital. Other hospitals have large amounts of laundry and linen costs and supply costs in the dialysis department, even though the dialysis unit may not use those supplies, primarily because it has been favorable to the hospital's overall reimbursement to do their accounting in that fashion.

So we believe that with better accounting and more efficiencies in the program, most hospitals would likely not have to come in for an exception. But we do think the rates are right at the appropriate level.

Mr. **Martin**. It would certainly be your expectation that the administration of any hospital which believes they would have to close their doors because of this lower limitation before they do that would probably come to you and file for an exception, make a case, and show you what their audited figures are for their costs; is that correct?

Ms. **Davis**. Yes. We would anticipate that is what they would do.

Mr. **Martin**. There has been the counter argument here that instead of lowering the screen, for various reasons you should increase it. Now, if you increase it, you will have fewer people filing for exceptions. But would it not also be true that all of those who now take the $138 without objection would probably take whatever higher number you allowed, too?

Ms. **Davis**. That is correct. That is why we believe it is not prudent to pay additional dollars, but rather, if we were to err, to err under the assumption that those facilities who needed more would file for an exception.

Mr. **Martin**. An earlier panel including Mr. Green advocated that there ought to be a payment to the doctor for the inconvenience of attending patients with home dialysis. And Dr. Blagg also spoke to that. As I understood his comment, he refined that to giving an equal payment to the doctors for home dialysis.

If I understand what you are saying, is that what you are proposing?

Ms. **Davis**. Yes, sir, it is what we are proposing. We are trying to remain neutral. And what we believe is the fiscal disincentive has been there in the past for the physician to make the decision when it would definitely impact on their own pocketbook.

Mr. **Martin**. So you agree with Mr. Green and Dr. Blagg on that?

Ms. **Davis**. What we have defined as the capitated rate would be the same, whether the patient was an inpatient or a home dialysis patient.

Mr. **Martin**. Dr. Freeman of the Association of Renal Physicians, who will speak later, will criticize, as did Dr. Newmann earlier, that the data on which you base your regulation is 4 years old, that it is 1977 to 1979 on average, with no adjustment for inflation. And if there is some explanation as to why that might be, I would like to hear it.

Ms. **Davis**. Actually, the data is 1979 data. When I came into this position last spring, I found that, although the Congress had directed HCFA to come up with a prospective rate in 1978, nothing had yet been accomplished in this area. So we made the decision that, although the audit data we had was somewhat aged, we believed it was the best data we could produce. To delay we felt was an inappropriate decision to make.

If one were to go to a full-scope certified audit, then it would cost us $3 million and take us another 6 months. That kind of a delay in moving to a composite rate would cost roughly $68 million. It was my decision to go ahead on the data we did have, recognizing fully that we would try to recognize the slight aging in the data base.

And we believe we did that. We added a 5-percent factor for the hospital component. We did not add an additional one for the independent facilities because they already, we felt, had been recognized by putting them in the same strata with the hospitals, when we did the initial base. But we do feel that our rate is a fine line between fiscal prudence and having to guarantee access to the patient.

Mr. **Martin**. Thank you, Dr. Davis.

Mr. Chairman.

Chairman **Rangel**. Mr. Pickle.

Mr. **Pickle**. Dr. Davis, how long have you been working on these rules and regulations?

Ms. **Davis**. Mr. Pickle, I have been working on those since I first walked into the office last March of 1981. I think Mr. Streimer may have been working on them even longer, perhaps. But it has been a rather significant amount of time and effort by a number of people in our agency.

Mr. **Pickle**. For a year or two?

Ms. **Davis**. For a year or two, yes.

Mr. **Pickle**. And I assume both the hospital physicians and patients are mindful that you are trying to arrive at some kind of a new approach?

Ms. **Davis**. I spent a great deal of time last summer meeting personally with those groups. I think I met with most of the major organizations, as well as patients' groups.

Mr. **Pickle**. You have now issued the proposed rules and the comment deadline has been closed.

Ms. **Davis**. Yes.

Mr. **Pickle**. But in the meantime you have also been advancing a study to see how these rates would affect the hospitals if there should be some kind of exception made in the meantime.

Ms. **Davis**. Yes.

Mr. **Pickle**. Based upon conversations you had with Mr. Rangel some time ago, you indicated you may well follow the exception route. Is that to say it is reasonable for us to expect that these hospital-based facilities would be given time to adjust, that you would not expect them to comply with it overnight?

You said you are offering a delay of some time to try to adjust to these proposed rates.

Ms. **Davis**. What we indicated was that, although the rate was published last fall in the NPRM, and we did feel that was a sufficient length of time before issuance of the final regulations. However, the number of comments we received indicated the facilities still have a concern for that and we are willing to look at that as we look at all of the other comments.

Mr. **Pickle**. You said you are willing to look at it. Does that mean you will consider some kind of a phase-in period to allow the hospitals to adjust?

Ms. **Davis**. We are willing to take that into consideration. I cannot make a final decision, nor would it be appropriate for me to preempt the Secretary's final decision on this. But I am certainly willing to take this into consideration.

Mr. **Pickle**. Based upon your comments, you have offered the Secretary this option, have you not, and you will recommend that that is one consideration?

Ms. **Davis**. We have not made any final policy calls, because we have only completed the deadline. In terms of the time, it will take us 2 months, roughly, to analyze all of the comments. So I have not yet made any recommendations to the Secretary in terms of what the final regulation will look like.

Mr. **Pickle**. Now, in the proposed regulations have you in effect reduced the reimbursement to the physician?

Ms. **Davis**. That is a rather complicated answer. Let me clarify it. In some cases yes and in others no, because in moving from the initial method to the ARM method it does mean that some physicians by virtue of referring patients to home dialysis will be picking up an additional source of funding.

Mr. **Pickle**. I thought someone said this morning that the physicians' level of reimbursement had been the same for 5 or 10 years. I have forgotten the period, but for some time it had been steady and there had been no adjustment for inflation costs or other factors.

Ms. **Davis**. That is correct.

Mr. **Pickle**. Now, if you have kept the physician at that level——

Ms. **Davis**. Since 1978.

Mr. **Pickle**. That is 5 years. It looks like under the proposed rules you are going to be putting more emphasis into home dialysis, and that home dialysis really cannot work unless they can operate from a hospital, some kind of a facility. They have to report back to a unit. And if you weaken that hospital unit both in the reimbursement to physicians and in the rates, will you not make it difficult to keep many of those hospitals open.

Ms. **Davis**. We do not believe we are weakening it. What we are recognizing is, for the physician referring a patient for home dialysis care we will now pay for that care equally to what we would pay for their care in the inpatient facility—excuse me—for the in-hospital or in free-standing facility.

Mr. **Pickle**. When you give them that treatment at home and maintain the rate, you still have reduced, in effect, the reimbursement value to the hospital, because the other costs have gone up, not only because of inflation, but because the hospital has to take care of these severe cases and a lot of other factors that keep its costs up.

It just seems to me like somewhere in the process—and I have not talked to physicians—but it seems you are weakening hospitals and in turn physicians in order to encourage home treatment as the methodology. I think home treatment probably is the methodology, but it ought to be balanced.

It seems to me at this point we would need a good transition or a period of adjustment for the hospitals, regardless of what we ultimately do.

Ms. **Davis**. Mr. Pickle, I think we indicated we were willing to look at that as a possibility. In going back, however, to your comments relative to the physician, we believe that the amount that is being paid to the physician for those physicians who have more patients to refer for home dialysis care, that those physicians will experience an increase in income over the past, because in the past they have not received the same reimbursement for home dialysis patients.

And I would also point out that for those physicians, they do not have to go out to the home and see the patient in the home each and every treatment. They can supervise those patients from the facility itself.

Mr. **Pickle**. That is right. But if the facility is weak, eventually they may not have the facility from which to operate. You will always have some patients going to and from hospitals.

Ms. **Davis**. I understand your concern. We do not believe the rates will weaken the facilities. We believe it will give the facilities incentive to practice more cost efficient behavior than they have in the past.

Mr. **Pickle**. I thank you, Mr. Chairman.

Chairman **Rangel**. Doctor, I was reviewing a letter I received from the Secretary and he indicated he was looking forward to sharing with me the comments, through you, at this hearing he would have in connection with a letter I sent. I assume we can conclude by saying that, as it relates to the problems of additional expenses, that a separate study is going on there.

As Mr. Pickle was asking, is it possible to phase in this program, to have a transitional period so that the patients, doctors and providers can educate each other? Is it possible? Is it being considered?

Ms. **Davis**. It is certainly one of the things we will take under significant consideration. But I cannot yet speak for the Secretary.

Chairman **Rangel**. I understand that the exception is a possible vehicle of flexibility and that pediatric facilities and hospitals might get equitable consideration under that. I had a hard time getting people to say that pediatrics was an exception. I guess you just assumed I would know that.

But do you intend to have standards so that other people would know what could possibly be considered an exception?

Ms. **Davis**. We listed in the NPRM those four factors. We clearly indicated one would be the atypical patient mix. In terms of what is a standard mix, frankly we could not come up with anything we found any group of people could agree with. And as I gathered today, people could not agree with what is a typical patient mix and what would be atypical.

What we have clearly indicated is that we are willing to entertain the exceptions process. We tried to say the atypical patient mix was one. It is up to the facility finally to indicate to us how their patient mix is atypical. Again, if it is a sole community provider that would be another exception.

Chairman **Rangel**. The annual cost data, you have worked that into the system so that next year you will have better information. And why did you say that the reimbursement provision was not adopted for home dialysis? We have witnesses saying it would be cost effective for the Government, but would increase the costs for the patient.

Ms. **Davis**. I am sorry? I did not hear the beginning.

Chairman **Rangel**. One hundred percent reimbursement for purchase of home equipment. Witnesses have said that there may be some long-term cost savings, but certainly the patient should have a little incentive, too. And what you are doing is increasing the patient's responsibility.

Mr. **Streimer**. We have found in the past that provision is extremely difficult to administer, because we must keep track administratively of every machine. We will not take the machine away from any of the 750 people who currently have one.

For new people we understand several things may happen. Facilities may buy the machines themselves and receive the full composite rate, of which some component is for the machine. Additionally, we understand from the largest machine manufacturer in the country that they are putting together a marketing plan that would put a machine, with all the supplies and equipment, through a facility to any home patient for in the neighborhood of $85 to $95.

Chairman RANGEL. Are you saying a patient would not have to buy a machine?

Mr. STREIMER. That is correct.

Chairman RANGEL. Could we provide something there to encourage them not to buy it, but to make certain they do not have to pay the 20 percent? Why should a patient be denied incentive when the providers are given incentives?

Mr. STREIMER. We are looking at the 100-percent machine issue closely. It is difficult to administer and we are sensitive to the fact that for that patient who would want to buy outright his own machine a certain benefit is being diminished here, and we are looking at that.

Chairman RANGEL. All right.

Mr. Martin.

Mr. MARTIN. Thank you, Mr. Chairman. A little earlier you were questioning Dr. Davis and her associates about the pediatric hospital situation.

And as I understood your reply, you stated a willingness to receive exception petitions from those easily identified as pediatric hospitals. Would it not be just as easy to allow a separate rate for pediatric hospitals? It seems to me even if it is only 15, that is almost 15 that would not require your administrative cost of review, and certainly it would save them from having to prepare a case that you anticipate will be accepted anyway.

Would it not be better to make some allowance for that in the rate structure? I know it complicates the rate structure, but if you could identify what is a pediatric hospital, wouldn't it be easier.

Ms. DAVIS. We did consider that, Mr. Martin. But the difference in cost is rather significant between those 15 hospitals, and to arrive at one rate which we felt would apply to all was very difficult. And we felt that rather than do that and perhaps reward some and penalize others, since there were just the 15, we would work through the exceptions process.

Mr. MARTIN. Did you consider doing the same sort of thing for the rural facilities? I expect there are a lot more of those, perhaps a couple of hundred. But once again, you recognize that because of their lower degree of utilization if you put a screen, a ceiling on them and they have to be screened to get through that ceiling, you know they are all going to be coming in for an inception, do you not?

Ms. DAVIS. The impact on the rural hospitals came about largely as the result of using the wage index. And frankly, that is something we have just become aware of. We will be taking a look at that. But I would remind you that that was language in the committee report that told us to take into consideration the area wage factor.

We will restudy that issue and perhaps arrive at some conclusions as to how we can meaningfully adjust that.

Mr. **Martin**. You are not allowed to take into account the degree of utilization?

Ms. **Davis**. No.

Mr. **Martin**. Because the degree of utilization would take the cost per patient up, so, that, it seems to me, should be taken into account. You could save yourself a lot of paperwork and save them a lot of paperwork if you could anticipate a fair rate for those kinds of isolated rural facilities.

Mr. **Streimer**. As Dr. Davis mentioned, we have the exception criteria. The big problem in trying to make judgments——

Mr. **Martin**. But the point I am trying to make is, with the exception criteria——

Mr. **Streimer**. They have to come in.

Mr. **Martin**. Not only that, but they must bring in a lot of paperwork to support their application.

Mr. **Streimer**. The important consideration that must be appreciated here is the fact that the composite rate structure makes every facility unique solely because of the percent of patients they have in-center and at home. Two very similarly situated rural facilities—one of which has a great percentage of patients at home will likely need no financial relief, even though they may be a sole community facility in a low-wage rural area. A facility in another rural area not able to send any patients home for good medical reasons may indeed need relief.

So the nature of the composite rate makes every facility which otherwise might look similar, it really does make them quite different in terms of their revenue receipts under the composite rate structure.

Mr. **Martin**. Those are all the questions I have.

Chairman **Rangel**. Doctor, let me thank you on behalf of the committee. As you know—and I was surprised to see that you had received the brunt of some of the patient's concern the way I have. I did not know they knew how to get to your office as easily as they did to ours. I have not referred them to you.

Ms. **Davis**. I appreciate that.

Chairman **Rangel**. Yet. [Laughter.]

What has happened, however, is constituents who have had concerns have contacted their members, and their members, as we all do, have contacted members of the Oversight Committee. And the Speaker was one of those members who had been educated by his constituents about the possible closing of these centers.

What I did for the members to use is to send them a copy of a letter I sent to the Secretary, and then the Secretary sent me a letter indicating his willingness to work with staff to overcome the fears and to try to make certain before anything was finalized that at least there was a cooperative effort being made by the administration and by staff, who have more expertise in this area than members do, to listen to all of the parties.

I am satisfied that you have the same sensitive concern, and I do recognize that you work under a terrific burden, that it is resented by the Office of Management and Budget and other considerations in terms of the overall deficit.

My staff is prepared to sit with your staff and I hope we can find language that will not change the thrust of what we are attempting to do, but to try to explain in layman's terms what these exceptions could be, what it means if there is a sole provider, to indicate to hospitals that provide a specialized type of care, not for the hospitals but at least for the constituents with children in these hospitals, that we can agree on some language; and to say that the member and the committee was involved and we have some assurances the administration is just as concerned.

If there is a breakdown in communication, the other information will be sent to members. Your name is not mentioned. It is to the Secretary. This is a rough year for all of us. But people are concerned with their lives and we are concerned with our survival, and it may be easier for you to provide the answers directly. We hope that will not be necessary.

I sincerely want to thank you for the sensitivity you displayed and your willingness to cooperate with the committee in trying to resolve this issue.

Ms. DAVIS. Thank you, Mr. Chairman. I know this is a significant concern to you and you have taken a great personal interest in this area, and I appreciate your concerns and we will stand willing to discuss these issues with you.

Chairman RANGEL. Thank you.

Mr. PICKLE [presiding]. We will ask the witnesses and our audience to resume their seats. We have one more panel to present this afternoon. This panel consists of Dr. Richard Freeman, president of the Renal Physicians Association. Dr. Freeman?

Dr. RICHARD B. FREEMAN. Yes, sir.

Mr. PICKLE. And then Mr. Donald Simmons who is administrator, El Camino Dialysis Services and a past president of the Renal Administrators Association; and Dr. James Cerilli, past president, National Association of Transplant Surgeons, who is a professor of medicine at Ohio State University. We also have Dr. G. Marshall Abbey, vice president, Baxter-Travenol Laboratories. And I believe you are accompanied by Dr. Karl Nolph, a professor of medicine, University of Missouri.

And one more panelist in this same group will be Dr. Jack Moncrief, who is my good friend and a physican from Austin, Tex., codirector of the dialysis system at Austin Diagnostic Clinic and head of that nephrology division, and one of the national literates of this home dialysis system. I welcome you here and appreciate your contribution to this overall field.

We will proceed with the statement from each of you. Do you have a statement you wish to summarize or present to us, Dr. Freeman?

Dr. RICHARD B. FREEMAN. Yes, sir.

Mr. PICKLE. Let me say in the beginning your entire statement will be made a part of the record, if you wish to summarize. I know we are running late. Chairman Rangel asked me to express that to you. We will stay with you through the panel, but this takes time to get on the record. I know you understand that.

Dr. RICHARD B. FREEMAN. I understand that. Yes, sir.

STATEMENT OF RICHARD B. FREEMAN, M.D., PRESIDENT, RENAL PHYSICIANS ASSOCIATION

Dr. **Richard B. Freeman**. Thank you. I am Dr. Richard B. Freeman. You heard from Dr. Richard M. Freeman earlier today. He is the president of the National Kidney Foundation. I am the head of the nephrology unit at the University of Rochester and the president of the Renal Physicians Association.

There are or were approximately 25 members in our organization in the audience, about 5 of whom have already made testimony. It is a broad-based organization representing 700 renal physicians, transplant surgeons and neurologists throughout the United States.

I would like to make two comments that are not in the record or not in submitted testimony that may help to clarify some of the misunderstandings that seem to have gone back and forth here today. It is not a good idea to categorize patients, but I will do so in an attempt to clarify this misunderstanding of need for hospital facilities and freestanding facilities and who can go home and who cannot.

Dismissing the home dialysis patients for the moment, it is clear that large hospital facilities that treat stable patients have no greater need for reimbursement, except for overhead charges, than does a freestanding facility. And I emphasize the stable patient.

There is a need, however, to maintain backup care in hospitals for those patients who are unstable—hypertensives, diabetics, those who have unstable treatment procedures. This group of patients may constitute 10 to 15 to 20 percent of the entire dialysis population. Hospitals are needed to take care of these people.

So that there is—and I would like to comment further on the exception problem that had been discussed later in the testimony.

The second item that came up in the last statement was that—I am quoting from the Federal Register regarding how old the data was. It was implied that the data was from 1979, from which the proposed rules were made. I quote from page 6565 of the Federal Register of February 12, I quote, "We consider whether an adjustment should be made specifically to account for any inflation costs that may have occurred since our audits were conducted of reports for fiscal years ending 1977, 1978, 1979." Therefore, the implication that the date is from 1979 is not correct. It goes back as far as 1976 and is therefore quite updated.

And if I could go on to the formal summary, short statement, Mr. Pickle. We realize that HCFA had a very difficult challenge to devise reimbursement regulations which are reasonable and noninjurious to the ESRD program, but still reflective of cost constraints. We believe HCFA has failed in this initial attempt and that proposed regulations are seriously flawed.

Some of our major specific criticisms of the proposed regulations as applied to facilities include the data used—and this is the point I just made—to justify the ratemaking is very outdated. Some of it is 6, maybe 7 years old, and there has been no consideration for inflation.

This stale data is very suspect since HCFA has made downward adjustments to the data because some of the costs were said to be medicare, nonallowable. These adjustments which amounted to more than $20 per dialysis for freestanding facilities were made unilaterally by HCFA without any opportunity for objection or contest by the providers in matters that are clearly not settled, either from a regulatory or a legal perspective.

The quality of the economic data utilized by HCFA is further tainted because it did not utilize statistically comparable data for the various components of its composite rate formulae. HCFA has made an artificial attempt to comply with the congressional demand for a dual rate by tacking onto the freestanding facility rate an arbitrary 5 percent for hospital-based centers.

Moving on to physician reimbursement, a subject which has not been touched on and which is a major thrust of my presentation. We believe that current members of HCFA have failed to research its own archives concerning the original premise upon which the alternate reimbursement method, the ARM, pays physicians for services rendered to chronic dialysis patients.

We can make this statement since we were involved, the RPA, with the Department of HEW in 1974 in developing the alternate reimbursement method. The ARM was devised to be analogous to a lawyer's retainer, a global or a comprehensive fee to take care of patients. Thus, the physician would receive a monthly fee for caring for his chronic dialysis patients, and this would cover actual hands-on services which is really a fraction of the time the physican spends on patients and cognitive services such as interpretation of the laboratory data.

The cognitive services may be defined as the entire expertise of the physician that required him to go to medical school, take a residency, train and gain experience to be able to interpret and assess the entire patient and their problem. In addition, he or she supervises the specific supervision of nurses, technicians, and other members of the health care team.

There are discussions with families, the physicians and his colleagues are on 24-hour call and there is a detailed continuing review and total assessment of the patient's medical condition. It was anticipated that the physician's compensation, which would average out under the ARM as fair as some patients would be complicated, requiring more time than the norm, and some patients would be more stable, requiring less than the norm.

We know from a freedom of information request that some of the current staff of HCFA have recommended a reduction in physician's fees in the proposed regulations because the number of direct contacts with the patients do not allegedly justify the fee. Therefore, it fails to recognize the other cognitive services that the physician provides.

They have made the recommendation—but at the same time they have acknowledged to us, the Renal Physicians Association—that HCFA did not have in its physician services audits cognitive services because it had not developed an audit methodology for evaluating cognitive services.

Clearly, in our opinion, the reduction, the total overall reduction in physician's fees, which will be 30 percent, is unjustified.

Further, we would like to note to Congress that HCFA has, with one small exception, failed to apply the medicare economic index to the reimbursement for renal physicians under the ARM. So that the renal physician has been reimbursed—the point that you made, Mr. Pickle—at the same rate for last 10 years.

A fuller explanation of the deficiencies in the proposed regulations are contained in our detailed document which has been submitted and which you have available to you.

From a positive perspective, we realize that reimbursement regulations must be put in final form in the very near future, and we would like to offer our suggestions for devising an acceptable set of regulations that would not compromise the care of patients in the ESRD program but still would be cognizant of cost constraints.

To device such regulations, HCFA must use current and accurate data, or alternatively, they must increase by an inflation factor some scientifically-derived cost data. This data must be analyzed by accepted statistical methods to appreciate complexities and the potential adverse effects on patients, on patient care, and an equitable reimbursement system must be devised.

To this end, we propose the creation of a task force composed of representative groups such as the Renal Physicians Association, the Patients Association, NAPHT, the National Kidney Foundation, and others to work with HCFA. We submit that many of the basic rate making concepts in the proposed regulations require extensive revision and that the revision requires the input of people who are expert in the area of delivering services. We believe this can be done in a reasonable period of time.

In the interim, we believe that HCFA should control the exceptions given to the hospitals where there is no evidence that the services provided are any different from those of a freestanding facility. However, it is essential that adequate leadtime be provided to make adjustments in their programs. Except for those cases in which an exception to the screen can clearly be indicated by medical evidence, because they see patients whose diseases are complex and require a degree of medical effort exceeding that normally required, maybe hemodialysis patients, they can do this by curbing exceptions and it should result in savings in excess of $50 million.

This, again, is a point that has been discussed and Mr. Rangel was very interested in, and we believe that this must be done very carefully with adequate leadtime. We feel that the broad expertise in our organization and other organizations should be utilized. We stand ready to cooperate in a meaningful dialog with those responsible for finalizing the new regulation. Thank you very much.

Mr. PICKLE. Thank you, Dr. Freeman. We are glad to get your report and your added statement to the testimony you submitted.

The next witness will be Mr. Donald Simmons, Administrator of the El Camino Dialysis Services.

[The prepared statement follows:]

STATEMENT OF RENAL PHYSICIANS ASSOCIATION

We realize that HCFA had a difficult challenge which was to devise reimbursement regulations which are reasonable and non-injurious to the ESRD program, but reflective of cost containment policies. We believe HCFA has failed in its initial attempt, and that the proposed regulations are seriously flawed.

Some of our major specific criticisms of the proposed regulations as applied to facilities include:

1. The data used to justify the rate making is stale, much of it being six years old and without any adjustment for inflation.

2. This stale data is further suspect since HCFA made certain diminishing adjustments to that data because some of the costs were supposedly not Medicare allowable. These adjustments which amounted to more than approximately $20 per dialysis for free-standing facilities were made unilaterally by HCFA without any opportunity for objection or contest by the providers of matters that are clearly not settled either from a regulatory or legal perspective.

3. The quality of the economic data utilized by HCFA is further tainted because it did not utilize statistically

comparable data for the various components of its composite rate formulae.

4. The artificial attempt by HCFA to comply with the Congressional demand for a dual rate by arbitrarily tacking on to the free-standing facility rate an extra 5% for hospital based centers.

Turning to physician reimbursement, we believe the current members of the HCFA team have failed to research its own archives concerning the original premises behind the Alternative Reimbursement Method ("ARM") which is paid to physicians for services to chronic dialysis patients. We can make this statement since we were involved with the Department of HEW in 1974 in developing the ARM. The ARM was devised to be analogous to a lawyer's retainer. Thus, the physician would receive a monthly fee for caring for his chronic dialysis patients and this fee would cover (a) "hands on services," i.e., direct patient interface, (b) cognitive services, such as review of a patient's lab and chemistry results and specific supervision of nurses and technicians regarding a patient's medical problem, (c) being on 24-hour call, and (d) detailed and continuing review of a patient's medical condition. It was anticipated that the physicians compensation would average out as fair as some patients would be difficult requiring more time than the norm, and some less than the norm. We know, from a freedom of information request, that some of the current staff of HCFA have recommended a reduction in physician fees under the proposed regulations because the number of direct contacts do not allegedly justify the fee. They have made the recommendation while at the same time acknowledging to this Association that HCFA did not in its physician services audits deal with cognitive services because it had not developed an audit methodology for evaluating cognitive services. Clearly, the reduction of physician fees is unjustified.

Further, we'd like to note to Congress that HCFA has with one small exception failed to apply the Medicare economic index to the reimbursement for renal physicians services under the ARM to chronic dialysis patients so that the renal physician has essentially been reimbursed at the same amount for the last ten years.

A fuller explanation of the deficiencies in the proposed regulations is contained herewith as Attachment A.

From a positive perspective, realizing that reimbursement regulations must be developed in final form in the near future, we would like to offer our suggestions for devising an acceptable set of regulations that would not be injurious to the ESRD delivery system, but would be cognizant of cost constraints.

To devise such regulations, HCFA has to use current and accurate cost data or alternatively increase by an inflation factor older cost data. This data must be utilized in statistically valid ways. HCFA must make an effort to draw on the resources of those who have complementary expertise to its own. To this end, we propose the creation of a task force composed of such representative groups such as RPA, NAPHT, NKF and others to work with HCFA. We believe that many of the basic rate making concepts encompassed in the proposed regulations must be revised extensively by HCFA with the aid of this task force. We believe this can be done within a reasonable period of time.

In the interim, we believe HCFA should control exceptions to the current reimbursement screen, with adequate lead time for providers to make appropriate adjustments for their programs, by curbing exceptions, except for those providers that can justify an exception to the screen by corroborated medical evidence indicating that they are treating dialysis patients whose diseases are complex and require a degree of medical effort exceeding that normally required by chronic maintenance dialysis patients. We believe the savings effectuated by this effort will be in excess of fifty million dollars.

ATTACHMENT A

COMMENTS REGARDING PROPOSED RULE FOR PROSPECTIVE REIMBURSEMENT FOR DIALYSIS SERVICES

The Health Care Financing Administration ("HCFA") published a Notice of Proposed Rule Making ("NPRM") on February 12, 1982 which proposed major changes in the reimbursement structure for dialysis services rendered pursuant to the End-Stage Renal Disease ("ESRD") program of Medicare (hereinafter referred to as "the proposed rule"). See 47 Fed. Reg. 6556 (1982) (to be codified in 42 C.F.R. Part 405). The proposed rule states that it implements section 2145 of the Omnibus Budget Reconciliation Act of 1981 (Pub. L. No. 97-35, enacted August 13, 1981) and is intended to improve the administration of the program and control the "rapidly growing costs" of furnishing dialysis.

The dubious assumption upon which the proposed rule is based is that the change in methods of reimbursement will not adversely affect facilities providing dialysis services or physicians treating patients with end-stage renal disease. An analysis of the proposed rule and discussions with physicians and providers (including free-standing and hospital-based) by the Renal Physicians Association ("the Association") clearly indicate a contrary result, however. Because of the potential adverse affects of the proposed rule upon patients, physicians and facilities, the Association believes it incumbent upon it to comment on what it believes are major defects in the proposed rule.

The comments of the Association address the following issues: (1) the deficiency of the audit data upon which the proposed prospective rates for facilities are based; (2) the faulty methodology of the proposed prospective rates for both facility and physician reimbursement; (3) the shortcomings and ambiguities of the regulations implementing the proposed rule; (4) general comments about the approach of HCFA in its attempt to implement section 2145; and (5) positive recommendations to achieve the cost savings desired with respect to the ESRD program as an alternative to the proposed rule.

I. THE DATA BASE USED IN THE DETERMINATION OF THE PROSPECTIVE RATES IS DEFICIENT.

In March, 1980, HCFA selected a stratified sample of 110 dialysis facilities for audit. The purpose of those audits was to provide audited cost data for facilities reimbursed under the ESRD program. The cost data resulting from those audits formed the basis for the proposed prospective rates set forth in the NPRM.

A. The Audits Conducted Were Limited In Scope.

1. REFERENCE: NPRM Section III.D. (47 Fed. Reg. 6562).

2. COMMENT:

The audits of the 110 facilities conducted by HCFA consisted of desk reviews of the form HCFA 9734 submitted by hospital-based facilities and a reconciliation of the form HCFA 9734 submitted by free-standing facilities with either their general ledger or an audited financial statement. It is the understanding of the Association that those audits were conducted under severe time constraints. Because of the manner in which the audits were conducted and the time limitations imposed on the auditors, facilities were not able to fully discuss and explain the costs reported. Moreover, facilities were not given the opportunity to challenge the audit adjustments made by HCFA which reduced costs. The audits thus resulted in unilateral adjustments (which were in reality, Medicare accounting assertions) by HCFA to reported costs with average reductions in free-standing facilities' costs of 15% or approximately $20.00 per treatment for a facility whose audited costs were at the median ($108.00/treatment). The Association believes that certain adjustments were made to the cost data of the facilities which were arbitrary and produced a "bare bones" median cost which was not representative of the actual costs incurred. (*See* Comment in section I.B., below).

Furthermore, it is the understanding of the Association that the Inspector General of the Department of Health and Human Services, albeit for other reasons, has similarly criticized HCFA for the limitation on the scope and quality of those audits and the resulting inaccuracies.

Therefore, the Association submits that HCFA should undertake a new, in depth audit of facilities' costs with close participation of the facilities and intermediaries in order to obtain valid cost data. This data should then be used by HCFA to develop a revised proposed rule.

B. Adjustments To The Cost Data By HCFA Auditors Were Baseless.

1. REFERENCE: NPRM Sections III.B., III.C. and III.D. (47 Fed. Reg. 6561-6563).

2. COMMENT:

The audit adjustments to the cost data resulted in total reported costs for free-standing facilities being reduced on the average of 15% and an average reduction of 3% in the costs reported by hospital-based facilities. Cost adjustments were reportedly made for payments for physicians' supervisory services, medical director compensation, and other costs which were considered to be Medicare nonallowable costs. Not only does the cost data not account for inflation, as discussed below, but it also disallows alleged Medicare nonallowable costs under the auspices of Subpart D of the Medicare accounting regulations. This reliance on cost reimbursement regulation accounting for a charge-based system has been in dispute since the inception of the ESRD program. The Association does not agree with HCFA that the concepts it has chosen to utilize are applicable to the program or that the issue is a settled one.

Reimbursement based on Medicare allowable costs without provision for a return on equity is an unacceptable position. Even though certain costs are categorized by HCFA as nonallowable (e.g., patient amenities such as T.V.'s, taxes, corporate stockholder servicing costs, bad debts, etc.), facilities nonetheless, incur these costs and they are taken into account in determining whether to provide services under the ESRD program. If such costs cannot be recouped through a charge-based reimbursement system by a return on equity and a realistic analysis of costs, facilities will not be able to cover their actual costs under the proposed system and will fold. This is particularly true in the case of proprietary facilities.

A further glaring deficiency in the audit analysis was the arbitrary limitation imposed upon a medical director's compensation of $32,000 per year. This was based on the assumption that the duties and responsibilities, and therefore the salary, of a medical director of a dialysis unit are universally analogous to that of an administrator of a 50 to 99 bed hospital in HHS Region I. This analogy is faulty. A medical director is required under 42 C.F.R. §§405.2102(r) and 405.2161 to be board-eligible or board-certified in internal medicine or pediatrics and to have at least 12 months of experience or training in the care of patients at ESRD facilities or to have served for at least 12 months as director of a dialysis or transplantation program. In addition to the medical background prerequisites, the medical director of a facility is required to undertake various medical related responsibilities over and above those of an administrative nature. These responsibilities include, among other things, participating in the selection of a suitable treatment modality for all patients, assuring periodic assessment of patient performance of dialysis tasks for self-dialysis patients, assuring adequate training of nurses and technicians and assuming "departmental" responsibilities over other physicians. These duties are all medically related and require far greater expertise than that of a lay administrator of a small hospital. A more appropriate analogous classification for a medical director would be that of the head of a department of a major hospital; a position that would command a salary far in excess of $32.000 per year.

Other arbitrary adjustments were made for hospitals' purchases of supplies which were allegedly out of line with those of other facilities and bad debts.

The Association submits that those costs were actually incurred by the audited facilities and should not be ignored, as HCFA suggests, in the context of a charge-based reimbursement system.

C. The Cost Data For Home Dialysis Is Not Representative Of Home Programs Nationwide.

1. REFERENCE: NPRM Section III.D. (47 Fed. Reg. 6563).

2. COMMENT:

HCFA states in the proposed rule that the median cost for home dialysis is about $97 per treatment. It is this median cost which is used in calculating the composite reimbursement rate. The use of this amount is clearly in error. First, the use of this median cost results in a distorted view of home dialysis costs toward the low end of the cost data spectrum. HCFA used cost data from less than 5% of the ESRD home programs which included 10 of the 13 largest and most efficient programs. These programs, by virtue of their size, can take advantage of certain operational efficiences and economies of scale, resulting in lower costs, which are not available to smaller programs. HCFA then further manipulated the data to achieve a low median by weighting the cost per treatment for home dialysis by the number of treatments. This technique is inconsistent with the methodology used for hospital-based and free-standing facility costs, which were not weighted on a number of treatments basis.

The result of this analysis of the cost data by HCFA is that faciliites attempting to increase their home programs have a cost median as a goal which is unrealistic with respect to most home programs since those programs will not be able, at least initially, to achieve the same efficiencies as the larger audited programs.

Also, the home dialysis data was not audited "due to severe time constraints" and there was no attempt "to establish rigorous comparable cost centers in any detail." See 47 Fed. Reg. 6563 (1982). This may have resulted in significant errors in the data and in unfair comparisons of the costs of the various programs audited because the types of services rendered by home dialysis programs may vary substantially.

These factors contributed to the inaccurate data used for the proposed prospective reimbursement rates and it is the belief of the Association that this data cannot be relied upon.

D. The Data Base Used By HCFA For The Prospective Rates Fails To Adjust For Inflationary Indices During The Period From The Date Costs Were Reported To The Present.

1. REFERENCE: NPRM Section III.D. (47 Fed. Reg. 6562).

2. COMMENT:

The proposed prospective reimbursement rates for facilities are based upon the cost per treatment medians derived from the audits which examined costs reported for various periods from 1976 through 1979. Therefore, the data used in computing the median costs for free-standing facilities and hospital-based facilities is six years old in some cases. Also, it is a mixture of several different years of costs for such facilities. This undoubtedly has resulted in an incompatible "stew" of data. Realizing that its information was not uniform by time period and was not adjusted for increases in the various inflationary indices from the point in time when the costs were reported to the present, the Administrator of HCFA stated in her Decision Memorandum to the Secretary of HHS in November, 1981:

> There are fairly persuasive reasons for using a percentage above the median. It would account for any statistical errors in our sample, any errors that the auditors may have made in adjusting costs according to Medicare principles of reimbursement, and provide some margin of fact that the data represented primarily 1978 and 1979 costs.

An explanation of the option to adjust the median cost to take into account these various factors was presumably given because the Administrator realized that adjustments were necessary in order to account for inflation and the other deficiencies in the audits. Yet, the NPRM has no adjustments to account for inflation!

The significance of HCFA's failure to account for inflation is indicated in Exhibit A attached hereto. Exhibit A clearly shows that the consumer price index and the medical care component thereof have increased substantially during the period of time in question. Failure to adjust for inflation renders the cost data utilized to formulate the prospective reimbursement rates arbitrary and inaccurate.

II. THE PROSPECTIVE RATE METHODOLOGY IS BASED ON FAULTY PREMISES AND CONTAINS NUMEROUS ERRORS.

A. The Use Of The Median Cost To Set The Prospective Rates Is Unrelated To Current Cost Experience.

As discussed above, the results of the audits of the 110 facilities have been used by HCFA in the calculation of the proposed prospective rates for free-standing and hospital-based facilities. However, no adjustment was made for inflation despite increases in prices in the intervening years as more fully set forth in Exhibit A. The failure of HCFA to acknowledge the increases in costs will result, according to HCFA, in more than 46% of the hospital-based facilities and 28% of the free-standing facilities being reimbursed at rates below their costs and potentially will result in those facilities having to close down. See 47 Fed. Reg. 6579 (1982).

Another significant factor for which the audit data failed to make adjustment was the inclusion in that data of facilities which reuse hemodialyzers and those which do not.

Reuse of hemodialyzers results in a significant cost savings, yet it is one which may be lost at any time and is not wholly in the discretion of the facility. Reuse of hemodialyzers can be constrained by state law or regulations (as it is in California, Colorado and Alabama), local medical custom, and patient recalcitrance.

Similarly, in other cases, state licensure laws prescribe physical plant requirements and staffing ratios for facilities which may result in nonallowable Medicare costs.

Hence, it may be extremely difficult for a facility to increase its economic efficiency and reduce costs in order to bring them below the prospective rates because of external factors which are beyond its control. This may result in a reduction in the availability of services in certain states.

B. The Use Of The Median Cost As An Equitable Benchmark For Reimbursement Is Questionable.

1. REFERENCE: NPRM Section III.D. (47 Fed. Reg. 6563).

2. COMMENT:

HCFA used the median value of costs in developing the proposed prospective rate. In the past, the Association has examined an array of costs of 295 facilities, and in those cases, the median and mean were approximately the same. In a small sample of 38 facilities, however, a median has little, if any, statistical meaning or validity. Since the mean cost figures in the audit might well have been substantially above the median, and since averages have always been used by HCFA in the past, we can only surmise that the median was really selected because it is simply a measure utilized to produce a lower value. The reliance on a lower value has little statistical justification.

C. The Proposed Prospective Rate Methodology Is Poorly Conceived.

1. REFERENCE: NPRM Section III. (47 Fed. Reg. 6561)

2. COMMENT:

The basic calculation of the proposed prospective rate is the sum of the non-labor cost per treatment component and the labor cost per treatment component, each of which is determined by multiplying the overall median cost per treatment for each component by the percentage of patients treated in either an in-facility or home environment for free-standing facilities and hospital-based facilities, respectively. However, the rate for hospital-based facilities has been arbitrarily adjusted so that a higher reimbursement rate is obtained. The purpose of the adjustment is two-fold. First, the adjustment is intended to accommodate the mandate of Congress that separate rates be promulgated for hospital-based and free-standing facilities.

Second, HCFA, in realizing the inadequacy of its data and methodology, proposed to adjust the hospital-based facility rate in two ways to attempt to correct errors in that data. HCFA stated in the NPRM:

> We propose to set the rate for hospital-based facilities at 105% of median costs. This adjustment to the initial rates is intended to accomodate the possibility that the methodology used has failed to recognize fully the legitimate costs of hospitals, either because

> of shortcomings in, or the age of, the data and the fact that the compositing structure forces the hospital rates below the median cost of all facilities. It is appropriate to use an adjustment for hospital-based facilities and not for independent facilities because hospital costs revealed by our audits tended to be relatively high, whereas median costs of the independent facilities were well below the payment rate proposed to be established. Therefore, any deficiencies in the data would impact the hospital-based facilities more than the independent facilities. In addition, the use of composite rates has a greater immediate effect on the hospital-based facilities, because the percentage of home dialysis patients is greater for hospitals than for independents. (This adjustment is in addition to recognition of $2.10 per treatment for legitimate access overhead cost, as discussed above.) 47 Fed. Reg. 6565 (1982).

It is clear that HCFA recognizes that the audit data and the methodology require adjustment in its application to hospital-based facilities. Its use of an adjustment, however, further impugns the proposed rule in that there is no basis, stated or in fact, for the use of 105%. This percentage is one which was arbitrarily conceived by HCFA with little or no basis except to recognize discrepancies in "audited" costs.

Furthermore, the stated rationale for the use of an adjustment factor is questionable. To say that the use of the composite rates will have a greater immediate effect on hospital-based facilities is debatable. In fact, free-standing facilities, which have 13% fewer home dialysis patients on the average than do hospital-based facilities, will in many cases experience a proportionately greater reduction in their cash flow reimbursement than will hospitals. Also, many free-standing facilities have fewer financial resources to withstand a decrease in cash flow than do larger hospital institutions or chain organizations.

The Association believes that the methodology used by HCFA in the establishment of the proposed prospective rates was designed solely to arrive at predetermined rates dictated by the need to show program savings. This artificial contrivance is not consistent with the intent of Congress and will impact adversely on the beneficiaries of the Medicare program who are receiving dialysis services.

D. The Methodology Of The Prospective Reimbursement Rate System Is Inconsistent With Congressional Intent.

1. REFERENCE: NPRM Section III. (47 Fed. Reg. 6562).
2. COMMENT:

Section 2145 of the Omnibus Budget Reconciliation Act of 1981 requires the Secretary to provide by regulation for a method for the payment of dialysis services on a prospective rate based on a single composite weighted formula for hospital-based facilities and a single composite weighted formula for other renal dialysis facilities. The Secretary was also given the option to propose another method of reimbursement. However, he decided not to exercise that option and instead proposed a composite rate methodology. *See* 47 Fed. Reg. 6561 (1982). The Congress further explained in the conference report accompanying the Act that a *separate* composite weighted formula should be calculated for hospital-based and one for other renal dialysis facilities but that both formulas would continue to take into account proportions of patients dialyzing in-facility and those dialyzing at home. It implies that to a certain extent, different considerations be taken into account in developing the rates.

Notwithstanding this mandate of Congress, HCFA has instead applied the same methodology and formula to both rate determinations except for some arbitrary adjustments. The Association does not believe this formula is consistent with the intent of Congress and suggests that it be withdrawn.

E. The Proposed Prospective Rate Does Not Adequately Account For Home-Training Costs.

1. REFERENCE: NPRM Section III. and Section V. (47 Fed. Reg. 6561, 6567).
2. COMMENT:

As HCFA is well aware, it is not feasible under the current reimbursement rate structure for all facilities to have home training programs. Such programs are costly and, in many cases, the costs exceed the established reimbursement rates. In those instances many facilities look to the reimbursement from the other support services rendered to home patients, delivered at a cost below the screen rate, in order to subsidize the substantial cost of the home training program. The Association is concerned, however, that under the prospective rates of the proposed rule, facilities with training programs will not be capable of recovering those excess costs. For example, under the current system, facilities without training programs refer home dialysis candidates to facilities that do have them. Since there is no major benefit to the referring facilities to provide follow-up care and other support services to those patients, the training facility that does provide those services is able to recoup costs of the training program. If, however, under the proposed rule there is a benefit to referring facilities in providing such services, the training facilities will lose those additional patients.

In that regard, the Association suggests that if the proposed rule is adopted, facilities with training programs be adequately subsidized to cover the costs of such programs which exist to train patients for other facilities.

F. The Exception Process Is Unduly Restrictive.

1. REFERENCE: NPRM Section II.C. (47 Fed. Reg. 6558).
2. COMMENT:

In the NPRM, the exception process has been revised and HCFA indicates that it expects under the proposal that "few facilities would be able to qualify for exceptions to their payment rates." 47 Fed. Reg. 6558 (1982) Certain examples of instances where an exception would be granted include an atypical patient mix (e.g., pediatrics dialysis unit), extraordinary circumstances (e.g., fire, earthquake, flood), isolated essential facilities or for certain types of educational costs.

While the Association agrees that the exception process has been abused and substantial increases in rates above the screen without adequate justification have been granted by HCFA in the past; nevertheless, the proposed rule swings the pendulum too far the other way. The Association believes, for example, that certain facilities, relatively few in number, do treat a substantial number of patients with complex diagnoses. The treatment of these patients requires an intensive effort which results in substantial additional costs. These situations should be recognized for exceptions without unduly burdensome justifications for the costs being required. The exception process and appeals process under HCFA's proposed rule does impose an unreasonable burden upon facilities to provide information indicating that their costs are not out of line with standards of other facilities with a similar patient case mix. Such a requirement has several inherent defects. First of all, if the costs are not out of line with facilities with similar patient mix, all of these facilities must be given exceptions and the issue becomes which would be the first facility to be granted an exception. Also, the proposed rule places the burden of obtaining the comparative information on patient costs upon the facility. This information, according to Administrator Davis in hearings before the House Intergovernmental Relations and Human Resources Subcommittee, was not available to HCFA, which leads one to ask the question of how a facility is to obtain that information. This is obviously an unreasonble burden.

Furthermore, assuming that the prospective rate methodology set forth in the proposed rule is adopted, then the exception process must also recognize the exceptional costs of those facilities, such as inner-city facilities, which are incapable of developing a reasonable number of home dialysis patients for reasons beyond their control. Without such recognition in the process, these facilities may not be economically viable.

III. THE METHODOLOGY USED TO DETERMINE PHYSICIAN REIMBURSEMENT UNDER THE PROPOSED RULE BY MEANS OF THE MONTHLY CAPITATION PAYMENTS IS FAULTY.

In the NPRM, HCFA proposes the concept of a monthly capitation payment for the payment of physicians who perform services for beneficiaries of the ESRD program. The proposed method of reimbursement is similar to the Alternative Reimbursement Method ("ARM") and is an attempt to implement incentives for physicians to encourage patients to go on home dialysis. The proposed method also applies a multiplier system but at a much reduced level. The Association objects to the proposed system for the reasons set forth below.

A. The Use Of A Multiplier Under The ARM Was Never Intended To Relate Directly To Physician-Patient Contacts.

1. REFERENCE: NPRM Section IV. (47 Fed. Reg. 6566).

2. COMMENT:

Under the ARM as it was conceived in 1974 with the participation of the Association, multipliers were used in determining the amount of reimbursement. The multipliers of 14 and 20 times the rate for physician follow-up visits were used in arriving at a monthly reimbursement rate because it was determined that the types of services (including specific procedures, cognitive skills and on-call responsibilities) provided by physicians in the ESRD program as well as the expertise of those physicians would be adequately compensated in that manner. At no time during the development of the ARM was the multiplier tied directly to the number of times that a physician monitored a patient during dialysis sessions. This is particularly evident in the case of home dialysis where, for the same monthly rate, the physician may only see the patient on a monthly basis, in normal circumstances, or numerous times when particular problems arise with that patient's treatment.

HCFA is now attempting to totally revamp this system by stating that a patient receives treatment on the average of 12.4 times per month and therefore a multiplier of 12.4 should now be used times the brief follow-up office visit charge (e.g., CRVS Code 90040) for each patient plus an intermediate follow-up office visit charge (e.g., CRVS Code 90060). That sum is then weighted based on overall in-facility and home dialysis percentages of patients. There are numerous drawbacks to this methodology.

First, the proposed rate setting methodology for the physician monthly capitation rate as articulated by HCFA totally eliminates the initial method of reimbursement. There is no statutory authority for this elimination. For that reason alone, the methodology of HCFA is defective.

In addition, the methodology is inconsistent with that used for the determination of prospective rates for facilities and no explanation is given for that inconsistency. In the case of facilities, percentages were applied to hospital-based facilities and free-standing facilities costs based on their respective percentages of patients being treated in-facility and at home. However, with respect to physician services, there is no differentiation between hospital-based and free-standing based physicians. Identical percentages of 83% for in-facility and 17% for home patients are used for both types of facilities in determining the rate. The result will be that the physicians in a hospital setting will receive the same amount of reimbursement under the proposed rule for proportionately less time because, based on the data in the NPRM, hospitals have 23.5% of their patients on home dialysis on the average versus 10.5% of free-standing facilities. In other words, physicians in free-standing facilities will be required initially to devote more time to the program for the same reimbursement because they have a greater proportion of in-facility patients who require more hands-on care and supervision than do home patients. This reimbursement system is obviously illogical.

Finally, the proposed rule states:

> Once a physician's rate is set by this methodology, it will be held constant and will not be automatically updated by the carriers' prevailing charges. The rate would only change when, after review of the rates, we determine that the data justifies an update. 47 Fed. Reg. 6567 (1982).

The Association strongly believes that this proposed rule continues to perpetuate a practice of HCFA which is in violation of statutory authority. The Social Security Act states that payments for physicians' services shall be on a reasonable charge basis and sets forth criteria to determine the amount of reimbursement for physician services. The criteria include the application of the cumulative economic index on an annual basis to prevailing rates determined by an intermediary. The purpose of the economic index adjustment is to reflect changes in expenses of a physician's office practice and general earnings level. The Association believes that Congress clearly indicated in the 1978 amendments to the ESRD program that the level of reimbursement for ESRD physicians under the Alternative Reimbursement Method should be based on a reasonable charge as adjusted by the cumulative economic index as applied to prevailing rates. Yet, despite its own regulations and statutory authority to the contrary, HCFA has not adjusted the rate for the ARM since July, 1978, while other physicians' reasonable charges have been adjusted consistently on an annual basis.

For the above reasons, the Association submits that the proposed rule dealing with rate setting for physician monthly capitation payments be totally revised. In that regard, the Association stands ready to work with HCFA in order to develop an equitable rate setting methodology which seeks to implement the intent of Congress as well as protect the continued viability of the program.

IV. REVISIONS TO 42 C.F.R. PART 405

In addition to the conceptual deficiencies of the proposed rule, the Association believes that specific language in the proposed regulations must, in some instances be clarified, and in other instances totally revised.

A. 42 C.F.R. §405.439

1. Section 405.439(e)

This section indicates that HCFA will reimburse each facility for bad debts up to the facility's Medicare allowable costs. The provision as it stands should be clarified to indicate whether all allowable Medicare bad debts will be reimbursed or whether there will be limitations on the amount of bad debts reimbursed even if they are all allowable under Medicare.

2. Section 405.439(h)

This section states that the jurisdictional amount for purposes of PRRB jurisdiction will be based on projected treatments for the exception request period. It would appear that historical data, e.g., past years' experience, would be a better indication of the number of treatments for jurisdictional purposes and the Association suggests that this regulation be revised to at least indicate that historical data will be considered.

3. Section 405.439(i)

This section states that if payment rates are revised based upon updated cost data, only a general notice will be published. It is the belief of the Association that any change in rates due to application of new data would be a substantive change and notice for public comment would be required under the Administrative Procedure Act. 5 U.S.C. §501 *et seq*.

B. 42 C.F.R. §405.542(c)(3)

This section states that factors used in determining the monthly payment amount may be adjusted as necessary to reflect certain changes. It is the belief of the Association that any change in the factors considered to determine the monthly payment amount would be a substantive change and notice for public comments would be required under the Administrative Procedure Act. 5 U.S.C. §501 *et*. *seq*.

V. THE PROPOSED RULE IS BASED ON INVALID PREMISES.

The basic conceptual premises of the proposed rule are: (1) that the ESRD program in its current form is incurring costs in excess of the value of the services provided; (2) that costs can be reduced without adverse impact on the availability of services; and (3) that modes of treatment are determined by the facility and/or physician for solely economic reasons. The mere statement of these premises show that they are spurious and set forth below is a discussion illustrating the inherent deficiencies of the proposed rule.

A. The ESRD Program Does Not Incur Excessive Costs Relative to the Value Of The Services Provided.

The concern of members of Congress and HCFA has been that the ESRD program is an expensive program whose costs must be reduced. Since the inception of the program, both the numbers of beneficiaries and the program's costs have increased dramatically. Total program costs have risen from about $228 million in 1974 to $1.5 billion in 1981 while beneficiaries have increased from 11,000 to 60,200. The costs per beneficiary have increased by approximately 20% during that period, yet during that same period of time, the consumer price index for medical services has increased 96%.

As a result, the ESRD program can be seen to have been particularly cost efficient. The magnitude of the efficiency is hinted at on page 6565 of the NPRM where HCFA states that "...evidence indicates the provision of services have been characterized by increased efficiencies." The current program has developed truly remarkable efficiencies which can be quantified using HCFA's own data. The program is efficient and to state that further cuts can be made to eliminate waste fails to recognize that participants in the program have held the line on costs.

B. The Mode of Treatment for Patients Is Not Determined Solely With Reference To The Economic Return Of A Physician And/Or Facility.

Both the proposed facility reimbursement rates and the physician reimbursement rate are based on the premise that home dialysis can be increased up to 30% to 40% of the patient population simply by action of the facilities and/or physicians. This is simply not the case.

In the case of a facility, it merely provides the equipment and personnel other than the physician which are necessary to perform in-facility dialysis and further provides the necessary administrative support to supply a patient with supplies for home dialysis. While it can be said that the medical director of a facility has input into the mode of treatment to be given to a patient, it is the patient's own physician and ultimately, and most importantly, the patient who is the decision maker. As a result, the facility is subject to the decisions of external forces which are beyond its control and to say that an incentive system gives it the ability to make or break its existence in the future totally misses the reality of the situation.

Administrator Davis, in her statement before the House Intergovernmental Relations and Human Resources Subcommittee, stated:

> The current reimbursement method provides an economic incentive for physicians to treat dialysis patients in a facility, rather than at home. This is inconsistent with the statutory goal to stimulate home dialysis. I believe we must deal with physician incentive as well as facility incentives because the physician is the primary decision maker on how treatment is to be furnished.

This statement of the Administrator underscores the tendency of HCFA to overstate a physician's control over patient treatment modes. First and foremost, the patient's own preference and his/her ability to deal with any particular mode of treatment determines the method of treatment. The Inspector General of HHS recognized this in his special delivery assessment findings to the Secretary in September of 1980 in which the Inspector General stated that there is no trend toward significantly greater client interest in home dialysis or kidney transplant.

Furthermore, the premise alleges that all physicians under the ESRD program make decisions based on economic considerations wholly apart from the benefit to the patient. This is contrary to the physicians' Hippocratic Oath and the AMA Code of Ethics and infringes on the physician's prerogatives on how to treat his patient. This proposed rule is also in direct violation of §1801 of the Social Security Act (42 U.S.C. §1395) which prohibits federal interference in the practice of medicine or the manner in which medical services are provided. By inserting itself into the determination as to who should be put on home dialysis, HCFA has violated this statute.

C. CAPD Is Not A Preferred Mode of Treatment.

The NPRM states that "CAPD is the preferred treatment for may [sic] patients." 47 Fed. Reg. 6568 (1982). In fact, CAPD is a relatively new mode of treatment with a medical technology which is in the experimental stages of its development and continues to be evaluated. CAPD has not yet proven its medical efficacy and time to do so is needed. Until an adequate period of time has passed in order to develop information and statistics on the mortality and morbidity of patients who are being treated for end-stage renal disease by CAPD, the Association strongly objects to its characterization by HCFA as a "preferred treatment."

In that regard, it is important that HCFA realizes that CAPD is certainly not appropriate for all, or even a substantial portion of, patients at this time and cannot be looked to as the mode of treatment which will reap substantial cost savings for the ESRD program.

D. Incentives Should Be Patient Oriented Rather Than Physician/Facility Oriented.

The proposed rule, as well as the statute on which it is based, assumes that the most efficient way to cut costs in this program is to impose "incentives" on facilities and physicians to lower costs. This basic premise completely misses the point. As noted above, the patient is a significant actor in the determination as to the mode of treatment. Therefore, incentives should be given to the patients to induce them to elect a less expensive mode of treatment, such as home dialysis. This has, in fact, been recognized by HCFA on page 6576 of the NPRM which states that "the lack of incentives to encourage Medicare patients to opt for a less expensive method of treatment such as kidney transplant and home dialysis" is one factor which has caused the escalating costs for the program. 47 Fed. Reg. 6576 (1982).

Under the proposed rule, this lack of patient oriented incentive will not change but will be shifted to others who are unable by themselves to effect the necessary savings. Nevertheless, numerous hospital-based and free-standing facilities would go out of business because of reduced levels of reimbursement which will reduce the availability of services in the program. Further, the quality of the services to be rendered may be severely impaired.

If, in the end, it is the intent of HCFA to reduce costs by reducing the availability and the quality of services, and thereby reduce the number of beneficiaries, the proposed rule will accomplish that goal.

E. The Proposed Rule May In Fact Increase the Costs of the ESRD Program.

One of the basic premises of the proposed rule is that facilities will be able to survive by requiring patients to go on home dialysis. We have noted above that that decision is beyond the specific capability of either the facility or the physician. Therefore, facilities will be required to cut costs by other means in order to maintain their availability to patients. Because one of the largest cost components of the program is labor, it is likely that labor will be the area where facilities will attempt to cut costs in order to survive under the proposed rule. In instances where the number of skilled personnel is diminished, the remaining personnel will be less able to help patients who are having difficulty during a dialysis session because their attention will be spread over a larger number of patients and their capacity diluted. With reduced labor, facilities will presumably be more fearful of having marginal patients undergoing dialysis, as will the physicians. They may therefore be more apt to refer those patients to hospitals for inpatient acute treatment. Without question, a patient who has to be admitted to a hospital or as an inpatient to receive dialysis treatments will be more costly to the Medicare program than will a patient who is part of an adequately staffed outpatient facility.

Exhibit B hereto clearly shows that inpatient costs should be considered when reimbursement revisions are contemplated. This integral part of the program is not mentioned in the proposed rules, yet it represents a significant portion of the total cost. It is essential in any policy dealing with the ESRD program that these costs be considered at the outset or the proposed rule will result in the mere shifting of costs of the program from outpatient facilities to an inpatient treatment setting.

VI. RECOMMENDATIONS

The Renal Physicians Association believes that an accurate data base should be developed and appropriately analyzed before complex formula rate making is attempted and that these proposed rules be withdrawn or held in abeyance pending the collection and analysis of that data. Nevertheless, the Association is cognizant of HCFA's need to implement immediate savings in the ESRD program because of current Congressional budgetary constraints. Therefore, the Association believes the current screen amount should be retained and proposes that HCFA generate the necessary budgetary savings as follows:

1(a). HCFA should eliminate exceptions for providers (a provider is intended to include both hospital-based and free-standing dialysis facilities) except for those providers that can justify an exception to the screen by corroborated medical evidence indicating that they are dialyzing patients whose disease is complex and requires a degree of medical effort exceeding that normally required for chronic maintenance dialysis patients. This exception should be granted only to the extent that the provider's direct cost attributable to the treatment of such complex patients is increased. We believe stringent governance of the exception process has the potentiality for saving 50-60 million dollars based on HCFA's cost reports.

However, we believe that a short transition period should be adopted before the imposition of the restrictive exception procedures, and that during this period bona fide applications from those providers meeting the restrictive criteria should be processed and approved to mitigate fiscal damage to the programs of those providers.

1(b). HCFA should also retain those exceptions for extraordinary events set forth in the proposed rule.

2. Additional reimbursement for routine laboratory tests such as hematocrits, clotting times, etc. can be eliminated. Thus, the reimbursement rate for chronic dialysis treatments would be deemed to encompass the provision of such routine laboratory tests. We believe the fiscal burden on providers will not be great, and that the potential cost savings would be substantial.

3. To the extent that the Congressionally required budgetary savings cannot be achieved by the savings generated by the reduction in exceptions, then the providers' screen should be reduced by a reasonable across-the-board percentage.

4. Physicians should be given a specific Medicare code number for the performance of their supervisory physician service to chronic dialysis patients regardless of the setting. The monetary evaluation for this procedure code should reflect the

cognitive skills that encompass the rendering of services to these patients, in addition to the specific "hands on" procedures. Further, this procedure code must be indexed under the Medicare economic index as are all other physicians services.

We believe for the reasons articulated above in our comments on the proposed rule that the proposed reduction in physician reimbursement is irrational, and particularly unjust because of the failure of HCFA (with one slight exception) to allow any cost of living increases during a ten year period. We also believe that the great bulk of the Congressionally mandated savings in the program can be achieved by the methods we have suggested above.

5. We would urge HCFA to work with the Association, the providers and patient groups to develop a workable and sensible rate making system once it has collected and analyzed accurate data.

CONSUMER PRICE INDEXES
1974 - 1981

YEAR	ALL ITEMS	MEDICAL CARE
1974	147.7	150.5
1975	161.2	168.6
1976	170.5	184.7
1977	181.5	202.4
1978	195.4	219.4
1979	217.4	239.7
1980	246.8	265.9
1981	281.5	294.5
% change 1974-81:	90.5%	95.7%

EXHIBIT A

END-STAGE RENAL DISEASE PROGRAM
QUARTERLY STATISTICAL SUMMARY

Entitlement

As of 12/31/81, the number of ESRD patients entitled to Medicare is 67,385.

Reimbursement

The following table shows reimbursement made by the Medicare program for the year in which services were provided to ESRD patients. This table is updated for bills posted through January 1, 1982.

Type of Payment (Millions)

Calendar Year	Inpatient	Outpatient	Physician* Supplier	Other**	Total
1974	$ 64.9	$ 135.5	$ 27.6	$ .5	$ 228.5
1975	99.1	205.2	55.7	1.1	361.1
1976	136.3	289.6	84.5	1.8	512.2
1977	164.1	368.0	106.5	2.4	641.0***
1978	207.5	452.7	133.5	2.8	796.5***
1979	261.7	556.7	180.2	3.6	1,002.2***
1980	328.7	658.4	231.3	4.4	1,222.8***
1981	297.2	522.0	202.9	3.5	1,025.6***

* Payments made on HCFA-1490

** Includes home health agency and skilled nursing facility payments.

*** Not final figures.

STATEMENT OF DONALD SIMMONS, ADMINISTRATOR, EL CAMINO DIALYSIS SERVICES, ON BEHALF OF THE NATIONAL RENAL ADMINISTRATORS ASSOCIATION

Mr. SIMMONS. Thank you, Mr. Pickle. My name is Don Simmons. I am immediate past president of the National Renal Administrators Association and on behalf of myself and the members of the association, I want to thank you for the opportunity today.

First, it is our opinion regarding the proposed regulation that the data and the methodology used by HCFA in developing these proposed rates are without merit, as to the validity of the data, by reason of obsolescence, and the methodology by reason of lack of consistency and reasonableness.

While this committee is the final arbitor of congressional intent, it seems to us that the concept of dual composite rates, as mandated by the act, has not been met by these proposed rates.

Second, we are very concerned that the stated objective of this committee to encourage the utilization of less costly treatment modalities will not be met by these proposed regulations.

We feel the 100-percent reimbursement agreement has been a positive factor in reducing a serious financial disincentive, both for patients and providers. We hope the committee mandates—I repeat, mandates—that the administration return this provision for all future home dialysis patients.

We have concerns that present rules concerning assignment of benefits by patients to providers other than those supervising their care may be counterproductive toward implementation of a fair and equitable reimbursement which would reward the efficient providers to both outpatient and home dialysis.

It is also our considered opinion that reimbursement of $20 more than the composite rate for a training dialysis will be a definitive disincentive to increased home dialysis. We know HCFA wants to turn the clock back to 1973 when 40 percent of the patients were at home, but it will not be accomplished by paying the same rates for training as were paid in 1973.

Third, we feel in order to minimize any disruptions to accessibility of care to ESRD patients that the proposed rates not be implemented for at least 6 months following the effective date of the final rules.

Fourth, as these rates are prospective and are based upon national data in the aggregate, we request this committee to seriously consider legislation that would prevent individual States from effecting statutes and rules which result in higher expenses for facilities without those individual States reimbursing the facilities for those increased expenses.

Finally, we would ask that return on equity be considered a reportable expense under the program. To proprietary facilities, return on equity is as much an expense as labor, supplies, or rent.

And I want to thank you again for this opportunity, Mr. Chairman.

Mr. PICKLE. I thank you, Mr. Simmons, for that brief statement. Now we will hear from Mr. Abbey, vice president of Travenol Laboratories.

STATEMENT OF G. MARSHALL ABBEY, VICE PRESIDENT OF TRAVENOL LABORATORIES, INC., ACCOMPANIED BY KARL D. NOLPH, M.D., DIRECTOR, DIVISION OF NEPHROLOGY AND PROFESSOR OF MEDICINE, UNIVERSITY OF MISSOURI; AND JACK W. MONCRIEF, M.D., DIRECTOR, CAPD PROGRAM, NEPHROLOGY DIVISION, AUSTIN (TEX.) DIAGNOSTIC CLINIC

Mr. ABBEY. Mr. Pickle, I am vice president of Travenol Laboratories, but the person who did the witness list was unduly kind to me. I am not a doctor.

Mr. PICKLE. I don't know if that is a compliment or not. They ask me, Mr. Pickle, are you a lawyer? I say no, I had the flu last week and I have not recovered yet. [Laughter.]

Mr. ABBEY. I hasten to add I have brought two distinguished physicians with me and I will introduce them in a moment.

Travenol Laboratories is a manufacturer of disposable dialysis supplies, both for hemodialysis and continuous ambulatory peritoneal dialysis [CAPD]. We supply hospitals, freestanding centers, and home patients.

Because we are a major part of the dialysis industry, we are interested in all changes within that industry, and therefore, I welcome the opportunity to be talking with the committee today.

Section 2145 of the 1981 Budget Reconciliation Act directed the proposal of new reimbursement rates which contain specific characteristics. First, the rate must be a prospective reimbursement rate. Next, it must be a composite rate. That is, reimbursement which is the same, regardless of the treatment location or the treatment modality. Third, it is to be a dual rate, one rate for hospital-based facilities and one for freestanding facilities. Next, it was to be a rate which encouraged medically appropriate home dialysis, and finally, it was to be a rate which accomplished significant budgetary reductions.

As the act which this Congress enacted earlier this year stated, the purpose of the reimbursement should be to encourage the more efficient delivery of dialysis services and to provide greater incentives for increased use of home dialysis.

In general, Travenol endorses the proposed regulation to establish prospective dual reimbursement rates and feels that it carries out the congressional mandate.

Now, I recognize, Mr. Pickle and Mr. Martin, that I might be perceived as part of a very small minority in taking the position of endorsing the proposed regulation. However, I would like to suggest to you and to the committee that this is not the case. We heard a number of witnesses today who were critical of some part of the proposed regulations. This is the way we govern our country in a pluralistic society. Each person has his own interest and it is appropriate that he pursue that interest before committees and before Congress.

However, the fact that should not be overlooked by this committee is that I believe every witness today has accepted the basic concept that we should have a prospective dual composite rate. That being the case, I would urge this committee to in turn urge HCFA to take a careful look at the various comments which have been made today about portions of the regulations which lie outside of the heart of the regulations themselves, apply the best judgment that HCFA and HHS can bring to bear, but then finalize these regulations and let us get the new reimbursement program underway.

I think it would be unfortunate if the approach mandated by Congress were further delayed simply because the regulation as proposed was unable to satisfy all of the parties involved. I think it is probably true that there is no way to write that kind of regulation.

Much of the discussion which you have heard here today relates to the issue whether or not the base rates of $128 for freestanding facilities and $132 for hospital facilities are the appropriate figures, and whether the spread between them is appropriate.

Travenol takes no position on that issue, except I do want to urge this committee and have urged HCFA to set a rate for hospital reimbursement which will insure that hospital centers remain in operation. As has been pointed out in other forums, hospital centers have 54 percent of all ESRD patients, but they monitor 70 percent of all home patients.

Freestanding centers, which have 46 percent of all ESRD patients, monitor only 30 percent of all home patients. To put that another way, hospitals send 24 percent of their patients home; freestanding center send 12 percent.

I would now like to introduce to the committee Dr. Karl Nolph, who is in a much better position than I am to comment on some of the medical aspects of the proposed regulation. Dr. Nolph is professor of medicine at the University of Missouri, and is also the principal investigator of the NIH-sponsored Patient Registry for CAPD. Dr. Nolph.

[The prepared statement follows:]

STATEMENT OF G. MARSHALL ABBEY, VICE PRESIDENT, TRAVENOL LABORATORIES, INC.

Mr. Chairman and members of the subcommittee:

I am G. Marshall Abbey, Vice President of Travenol Laboratories, Inc.

Travenol is a leading manufacturer of disposable dialysis supplies for hemodialysis and Continuous Ambulatory Peritoneal Dialysis ("CAPD"). We supply dialysis products for both center and home use.

I welcome the opportunity to appear this morning to comment on the proposed prospective reimbursement regulation for ESRD services published in the February 12 Federal Register by the Health Care Financing Administration. In general, Travenol endorses the proposed regulation to establish prospective dual reimbursement rates for maintenance dialysis services because it achieves the fundamental objectives of section 2145 of the 1981 Budget Reconciliation Act. I have the following comments and suggestions for improving the proposal.

1. General Comments

The proposal correctly implements section 2145 of the 1981 Budget Reconciliation Act and the accompanying expressions of legislative intent in the following respects:

It establishes a prospective reimbursement rate.

It provides for a composite rate; that is, the reimbursement rate will be the same regardless of the location or modality of dialysis.

It establishes a dual rate, one for hospital-based facilities, the other for free-standing facilities.

It seeks to encourage medically appropriate home dialysis.

It accomplishes significant budgetary reductions.

All of these features of the proposal -- and they are fundamental -- reflect the two legislative purposes of section 2145: to "encourage the more efficient delivery of dialysis services and [to] provide greater incentives for increased use of home dialysis..." (Section 2145 (a)(7)).

There has been a good deal of criticism of the proposal. Some of it seems justified to us, some not. Most of the criticism which has surfaced so far relates to whether the $132 and $128 base rates, and the $4 differential between them, are appropriate.

Travenol takes no position on these issues except to urge that the rates be set so as to keep hospital centers in operation since the hospital dialysis facilities have been responsible for most of the home dialysis service which is now provided. Hospital centers treat or monitor 54% of all ESRD patients, but monitor 70% of all home patients. Free-standing centers, which treat or monitor 46% of all ESRD patients, monitor only 30% of all home patients. To put it another way: hospitals send 24% of their patients home; free-standing centers send 12%.

A second criticism that seems to us to have some validity is that directed at the adequacy of cost data. It may be regrettable that the ESRD program, in ten years, has not collected definitive cost information. However, data deficiencies cannot hold back the proposed regulation any more than they have prevented establishing the existing reimbursement rates. We support the views expressed by the General Accounting Office and the Inspector General of Health and Human Services that the composite rate should be implemented and that, over the next year, better cost data should be developed to revise, as necessary, the specific payment rates.

I will note for the record, however, that the reported cost of CAPD is overstated. Table I reviews data which support an average cost on CAPD of $16,500 a year not the $18,250 stated in HCFA's proposal. This is a per equivalent hemodialysis treatment cost of $105, based on our own figures, versus $114 per treatment reported by HCFA.

Criticisms of methodology and data are the major points -- though by no means the only ones -- that have been made against the proposal. I believe that none of the criticisms and comments challenge the fundamental features of the proposed reimbursement system; it is prospective, composite and dual.

One criticism seems to us particularly misguided. That is that the composite rate will force medically inappropriate treatment at home. In part, this criticism is little more than dissatisfaction with changes in income that may be caused by the proposal. In part, it is the result of failing to recognize that the current reimbursement system actively discourages treating patients at home. In contrast, the essential objective of a composite rate is to allow physicians and patients to make decisions on treatment modalities with fewer economic constraints. We believe that this feature is essential to allow a competitive market to provide dialysis services to patients in the most efficient and medically appropriate way.

For some patients -- but not all -- treatment can most appropriately take place at home. Travenol believes that the developments of the past several years demonstrate that home dialysis -- both hemodialysis and CAPD -- are effective, viable modes of treatment for significant numbers of patients. Although the composite rate would indeed reduce the incentive for in-center dialysis, it does not force particular patients to be treated in any specific location. The proposal would allow the patient and physician to make this choice.

Because the viability of home dialysis is central to the composite rate, I would like to draw your attention to the list of states attached to this statement (Table II) and the corresponding percentages of patients on home dialysis. The figures were published in the New England Journal of Medicine and are based on HCFA and census data. In 1979, the national average of patients on home dialysis was 13%. Table II shows that the top ten home dialysis states had from 26% to 59% of their patients dialyzing at home. The national percentage of home dialysis patients is now about 19%, even with the current incentives for in-center dialysis and many individual states have home patient percentages far in excess of the national average. I cannot believe that these patients are at home because of inappropriate medical judgments.

The truth is that ESRD patients are at a high degree of risk and often have major complications. In addition, all forms of dialysis -- whether at home or in-center -- have complications. As we noted earlier, home dialysis, whether hemodialysis or CAPD, is not for all patients. There is, however, no doubt that it is a completely acceptable location of treatment for a significant number of patients. The composite rate proposal and the underlying legislation recognize this effectively for the first time.

2. Specific Suggestions for Changes

I wish now to turn to four areas in which improvements can be made to implement more fully the Congressional intent underlying the composite rate proposal:

- home training reimbursement
- initial equipment and "startup" costs
- treatment of complications, and
- transition preparations

A. Home training reimbursement

Home training reimbursement is inadequate to cover costs and should be increased. Moreover, the proposal encourages facilities to keep patients in training over an extended period because it provides for a $20 fee for each training session.

The longer a patient takes to train, the longer a center will continue to earn the $20 training fee and the more likely it is that the center will eventually recover its costs. We propose that facilities be paid a flat fee for each patient trained, without respect to modality and at the end of successful training.

B. Initial equipment and "startup" costs

Initial one-time costs of placing patients at home are not recognized under the proposal, and 100% reimbursement for home dialysis equipment is proposed to be terminated. "Startup" costs include specific products, such as scales and blood pressure cuffs, and the capital costs associated with equipment. Such costs cannot be recovered through the composite rate except over a long period of time. On the other hand, separate 100% reimbursement for dialysis machines, water equipment, and starter items, over and above the composite rate, would add significantly to program costs. Travenol proposes that these concerns be balanced by allowing for reimbursement, on a reasonable cost basis, for equipment and starter items, up to $3,000 per patient in addition to the basic composite rate. This will allow HCFA to address the concerns expressed over the termination of 100% reimbursement for hemodialysis equipment without complicating the basic composite rate system.

C. Treatment of complications

Under the proposed rule, facilities and physicians would not receive additional reimbursement above the basic composite rate for outpatient treatment of complications. On the other hand, if the patient is admitted to a hospital for the very same complication, drugs, additional physician visits, and other costs are reimbursed under Medicare Part A regulations. This results in higher costs for ESRD patients. Of course, some complications and some patient situations require inpatient treatment. However, wherever medically appropriate, the reimbursement system should support outpatient treatment. Therefore, we propose that reimbursement be made on a reasonable charge basis to both facilities and physicians for the treatment of significant complications on an outpatient basis. This reimbursement should apply to both home patients and patients dialyzed in outpatient centers. We have not made any estimate of the cost impact of this proposal, but because its effect would be to substitute outpatient care for more costly inpatient care which would otherwise occur, there should be a clear program savings.

D. Transition preparations

As you have pointed out, Mr. Chairman, many facilities may experience reductions in their per treatment rate under HCFA's proposal. Furthermore, the shift to a prospective rate could cause administrative dislocation at the intermediary and provider level, just at the time when Medicare contractor budgets are shrinking. This creates a risk of patient uncertainty. In addition, some centers will want to institute or expand home training capacities.

Without delaying promulgation and implementation of the composite rate, we believe that careful attention should be given to assuring a smooth transition to the new reimbursement system. We are not convinced that this requires a specific transition period during which the composite rate is postponed for all providers. Nevertheless, we believe that HCFA should engage in substantial advance preparations with its regional offices, medicare contractors, providers, and interested patient and other organizations in order to reassure patients and educate providers.

3. Conclusions

The extensive public reaction to the proposal that has already been voiced and our own review leave us with these concluding comments:

> ESRD patients are at high risk, not only from kidney failure, but from associated complications. Medical and patient judgment must remain at the core of choices about the modality of treatment that is best for a specific patient.
>
> There is a need for better data, both fiscal and medical, than we now have for the ESRD program.
>
> Inadequate though the cost data may be, the program must start somewhere, and it appears that the data utilized in the proposal is better than that previously used.
>
> The proposal achieves the fundamental objectives of the Budget Reconciliation Act.
>
> Further delay in implementing the composite rate system will further confuse patients, frustrate providers and postpone more efficient medically appropriate treatment for ESRD patients.

Therefore, Mr. Chairman, I request that you and your subcommittee urge HCFA to make the minor revisions suggested and promptly implement the dual composite rate regulations.

TABLE I

CAPD COST PER TREATMENT
(HEMODIALYSIS EQUIVALENT BASIS)

	HCFA ANALYSIS OF AUDIT RESULTS	TRAVENOL ANALYSIS OF HCFA AUDIT DATA	TRAVENOL TYPICAL CENTER ANALYSIS
Direct Home Support Costs	Not Available	$ 6.80	$ 10.04
General and Administrative Expense	Not Available	8.50	8.92
Sub Total Overhead	$ 22.91	$ 15.30	$ 18.96
Home Supplies	$ 86.78	$ 86.78	$ 84.28
Routine Laboratory Costs	$ 3.90	$ 2.00	$ 2.00
Total CAPD CPT	$113.59	$104.08	$105.24

KEY DIFFERENCES:

- HCFA imputed home support costs and general and administrative expenses for those programs which reported insufficient information. This skewed the results toward higher cost centers. Using either just the costs reported by those audited centers which reported data, or the results of a separate Travenol analysis of typical centers produces a significantly lower cost
- HCFA audited data includes some supply costs which have been marked up beyond the price at which Travenol sells directly to patients and centers, overstating median costs by about $1.50 per treatment.
- HCFA imputed lab charges at $3.90 based on their experience with hemodialysis. It is generally conceded that the current reimbursement system does not provide incentives for centers to contract for lab tests efficiently but encourages the use of related party laboratories at higher cost. Travenol believes that $2.00 per equivalent treatment is more indicative of the cost which can be obtained in an arms length transaction

TABLE II

Table 2. Dialysis Rates in the United States by State.*

State	Estimated Population in 1979 (Millions)	Number of Patients on Dialysis per Million Population	Percentage of Patients Having Home Dialysis	Transplant Rate per Million Population	Percentage of Dialysis Patients in "For-Profit" Units
Alabama	3.75	212	17	24	38
Alaska	0.38	52	20	0	0
Arizona	2.42	204	9	23	11
Arkansas	2.17	147	20	8	55
California	22.43	232	6	20	57
Colorado	2.73	190	23	19	52
Connecticut	3.10	207	5	15	15
Delaware	0.58	243	13	0	100
District of Columbia	0.65	983	3	122	53
Florida	8.77	274	6	11	48
Georgia	5.06	262	9	15	54
Hawaii	0.86	383	21	55	0
Idaho	0.90	67	23	0	0
Illinois	11.20	197	5	13	49
Indiana	3.40	172	43	16	0
Iowa	2.90	121	30	23	0
Kansas	2.35	130	26	8	4
Kentucky	3.49	119	9	21	60
Louisiana	3.99	238	6	15	58
Maine	1.09	121	8	15	53
Maryland	4.11	183	11	23	62
Massachusetts	5.76	223	10	27	47
Michigan	9.20	175	13	20	16
Minnesota	4.06	134	32	59	0
Mississippi	2.41	203	18	3	13
Missouri	4.85	170	21	26	10
Montana	0.78	109	38	0	0
Nebraska	1.56	113	6	23	0
Nevada	0.69	240	5	0	46
New Hampshire	0.88	85	8	0	73
New Jersey	7.31	242	14	11	24
New Mexico	1.23	173	13	24	62
New York	17.62	282	9	21	12
North Carolina	5.51	188	26	20	76
North Dakota	0.65	96	0	0	0
Ohio	10.72	155	11	24	14
Oklahoma	2.86	139	17	26	32
Oregon	2.52	138	26	27	35
Pennsylvania	11.72	210	14	18	21
Puerto Rico	3.32	159	9	3	64
Rhode Island	0.92	319	1	0	70
South Carolina	2.87	216	13	10	55
South Dakota	0.68	81	0	0	0
Tennessee	4.36	207	20	28	10
Texas	13.24	210	11	19	66
Utah	1.36	174	46	10	28
Vermont	0.49	122	28	22	0
Virginia	5.05	265	14	23	55
Washington	3.88	171	59	18	0
West Virginia	1.88	148	31	3	9
Wisconsin	4.72	120	20	37	9
Wyoming	0.45	20	0	0	100
Total	221.82	204.7 †	13.1 †	19.4 †	36.1 †

*All data were adapted from figures supplied by the End Stage Renal Disease section of the Health Care Financing Administration, Department of Health and Human Services, and from the Population Estimates and Projections, Series P-25, No. 876, February 1980, United States Department of Commerce, Bureau of the Census.

†Mean figures calculated from total numbers.

New England Journal of Medicine, 1980, 303:997.

Dr. Nolph. Thank you very much. I appreciate the opportunity to speak here today. I have supervised since January 1977 a CAPD program involving approximately 90 patients. With NIH support, I have directed multicenter evaluations of CAPD, and since January of 1981 I have been the principal investigator of the NIH-sponsored National CAPD Patient Registry.

Because the new proposed regulations will most likely increase the number of patients on CAPD, charges about the results of CAPD have been raised here today. I feel I am in a position to respond to those charges.

CAPD has received widespread acceptance by the medical community and is now offered in over 500 of the dialysis centers shown previously to nearly 6,000 patients. This is approaching 10 percent of the U.S. dialysis population. The numbers of CAPD patients in Canada as a percentage of the national dialysis population are even higher, approaching 20 percent, and similar figures are being approached in England.

It is hardly appropriate to refer to this therapy as still experimental. It was declared an alternative form of reimbursable therapy by HCFA in 1979 after a careful evaluation. I currently have patients in my program starting their sixth year on CAPD. The growth of CAPD has occurred in the United States in the face of inadequate reimbursement to facilities for CAPD.

The reasons for such growth include many medical advantages of continuous slow dialysis, the relative safety of the technique, the short training period, the fact that there is no need for blood access and no need for assistants and there is no need for expensive machinery.

For some patients such as the elderly with cardiovascular disease, diabetics, small children and patients living alone in remote regions, CAPD is, in many cases, the preferred therapy. If nephrologists wish to offer CAPD to selected patients whom they feel should be so treated in terms of their best medical judgment, then I would hope that new regulations would not continue the previous disincentives for this home form of dialysis.

I would like to conclude by responding to the allegations previously presented today that CAPD has extraordinarily high hospitalization rates, high dropout rates and may provide inadequate dialysis. The figures quoted in the previous testimony are supposedly from my registry, so I feel I am in a position to comment on these figures.

The figures quoted were from preliminary drafts of life table analyses which will be done when adequate data is available. Those forms, which were distributed only internally and not made a part of any formal report, were examples of the types of tables that would be used. But it was clearly documented that they were preliminary. In fact, the numbers are so small that by the fourth quarter of the year represented, the figures are dealing with only nine patients.

The first charge about high hospitalization days—let me comment in that area. It was pointed out that a high percentage of the patients are hospitalized during the first year. This is not surprising since the registery begins CAPD with training, which begins in the hospital. Therefore, the start of CAPD for many patients is in the hospital. They begin with hospitalization.

Also, in the hospitalization figures, training days are included. Again, the numbers are very preliminary. We have looked at the average number of hospital days in 562 patients followed over 299 patients years in a 9-month pilot study. The average number of hospital days per patient year was 25.7; only 50.4 percent of those days were actually related to CAPD complications; 6.7 percent were for training; 32.6 percent were for other medical problems which the patient could have on any technique, and 10.3 percent were for cardiovascular problems, which many of the patients on CAPD do have.

It is my own opinion there are no proven differences at present for hospital days between hemodialysis and CAPD, and until controlled, matched studies for age, presence or absence of diabetes and cardiovascular disease followups are done, there is no data to say whether hospital days are greater or less with CAPD than with hemodialysis.

Another interesting way to look at this problem is to look at free days that the patients have free of contact with the medical community. It is interesting to note that a CAPD patient has 12 clinic visits a year, and if you add 25 hospital days, that is a total of 37 contacts the CAPD patient makes with the medical community on the average per year.

The hemodialysis patient has 156 trips to the center, assuming they are on center hemodialysis. The testimony provided previously adds another 17 days in the hospital, so we are talking about contact days per year of 37 for CAPD and 173 for center hemodialysis. That is another way of looking at it.

Now, a word about dropout rates. The dropout rates projected on life table analyses were, again, preliminary ones, setting up formats. The data is just coming in, so the registry data quoted was very preliminary. In fact, in just the last few weeks, as more data comes in, the results are changing dramatically, showing that we cannot draw meaningful conclusions until more adequate data is available.

I do have a number of anecdotal reports of 2-year success rates in a number of CAPD programs—63 percent in our program, 76 percent in Toronto in diabetics, 62 percent in Toronto in general, and I would like to point out that the total success rates of patients remaining on CAPD are actually higher than patient survival rates on hemodialysis for the whole State of Michigan, as published in Kidney International just last month, where the 2-year survival of center hemodialysis patients was 54 percent. Our success rates of total dropouts is better than that.

I also would like to point out that, again, until randomized matched studies are done, there are no reasons why we can actually say that one technique has a higher dropout rate than the other.

The data quoted from our registry includes abandonment for all reasons, including good reasons—transplantation, and patients who recover renal function to the point where they no longer need dialysis. Also, you must realize that CAPD has a short training period and is so easy to provide that many centers put terminal cancer patients on CAPD. We have a high number of patients with leukemia, multiple myeloma, and terminal cancer. These patients are allowed the remaining months at home that otherwise would not be possible.

In spite of the high dropout rates—which again I insist we do not know are higher than hemodialysis—net growth does continue, so a number of patients do succeed.

Finally, I would like to comment on the challenge of inadequate dialysis. In my experience, most of my patients who switched to CAPD have increases in hematocrit, better blood pressure control, their strength improves, they gain weight, they increase their appetite, and in actual fact, clearances for many solutes on CAPD are much higher than for hemodialysis.

Many of the patients who have switched to CAPD from hemodialysis tell me they will not go back. That is, they want either CAPD or death. It is hard for me to believe that CAPD is inadequate for those people.

Survival—we have looked at the literature as to what is available, and it is interesting that of the figures I have found, there is no overlap between CAPD and hemodialysis in terms of 2-year patients survivals. The EDTA registry reports 2-year hemodialysis survivals in the 55 to 64 age group in 14,270 patients of 64.7 percent. I mentioned the Kidney International article of 54 percent in 1,560 patients, and in the whole State of Missouri, the 2-year hemodialysis survival is 57.5 percent.

Reports in CAPD for 2-year survival from our center are 85 percent, from our registry 90 percent, from CAPD 82 percent. There is no overlap. All of the patient survivals on CAPD are running higher. Again, I would be the first to point out, however, that until these are corrected for population characteristics, they do not provide any meaningful comparisons of the techniques.

If only 54 percent of patients survive on center hemodialysis, we know that there are additional dropouts for transplantation, and of almost 50 percent, 48.7 of our CAPD patients are transferred from center hemodialysis. It cannot be that good, and the dropout rates cannot be that much better than CAPD.

Finally, in this very last issue of the Annals of Internal Medicine, there is an interesting article which says that if you correct for age, the presence of diabetes and the presence of heart failure, it does not seem to matter what form of technique is chosen. And until we have studies that do correct for those variables, then all of these allegations quoting numbers from different sources do not provide much help.

Thank you.

Mr. PICKLE. Mr. Chairman, may I interrupt at this point? I have been given a copy of a letter written to Secretary Schweiker and it was a report on this continuous ambulatory peritoneal dialysis program. It was signed by Dr. Moncrief who is one of the witnesses, Dr. Nolph who has just been summarizing some of it, and by two other gentlemen, Robert Popovich and Mr. Keith Pyle.

I ask that this short report, the letter written to Secretary Schweiker, be made a part of the record. May I have permission to include it, along with the statement Dr. Nolph has made?

Chairman RANGEL. Without objection.

[The information referred to follows:]

THE AUSTIN DIAGNOSTIC CLINIC,
Austin, Tex., April 2, 1982.

Hon. RICHARD S. SCHWEIKER,
Secretary of Health and Human Services,
Washington, D.C.

DEAR SIR: We have been involved in the development and evaluation of Continuous Ambulatory Peritoneal Dialysis (CAPD) since its inception. We have also collaborated in the numerous studies of CAPD sponsored by the National Institutes of Health. At the moment, we are conducting the National Institutes of Health Registry of CAPD.

As you are aware; new proposed regulations for end stage renal disease (ESRD) reimbursement encourages home dialysis in contrast to the previous reimbursement policy. Because of the many concerns over reimbursement per se, some parties are challenging the proposed advantages of CAPD as an alternative form of home dialysis therapy and have proposed that the potential cost saving benefits of CAPD are outweighed by a high drop out rate and a large number of hospital days per patient year. Some individuals have expressed doubt relating to medical indications for, and efficacy of CAPD in the treatment of patients with ESRD. We would like to address some of these issues.

HEMODIALYSIS HAS MANY PROBLEMS

Hemodialysis is certainly not a trouble free form of therapy. Although it is difficult to determine drop out rates for chronic hemodialysis in this country, recent studies have reported mortality rates on chronic hemodialysis. In a report from the state of Michigan published in Kidney International (Vol. 21, p. 78, 1982) actuarial survival on center hemodialysis for 1,560 patients was 54 percent at two years. The 1981 Annual Report of the Missouri Kidney Program for the state of Missouri shows that two year cumulative survival on hemodialysis for 1,735 patients was 57.5 percent. Many of these deaths relate to cardiovascular problems often aggravated by the process of hemodialysis. Other problems with hemodialysis include repeated problems in maintaining a blood access, control of blood pressure, and recurring symptoms related to the rapid changes in body chemistries and fluid volumes which occur with the intermittent application of this therapy. Another unfortunate characteristic of chronic hemodialysis is the risk of sudden death. This may occur as a result of rapid decreases in blood pressure with resulting strokes and myocardial infarctions, sudden arrythmias, air embolis or massive hemorrhage into the dialyzer.

The problems with hemodialysis are exemplified by the rapid growth of Continuous Ambulatory Peritoneal Dialysis In just a few years, over 500 centers in the United States have initiated CAPD programs to over 5,000 patients. If hemodialysis were problem free, why would there be such interest in an alternative form of therapy? This is of particular significance since CAPD has had major fiscal disincentives related to its growth.

DROP OUT RATES AND CAPD

Under separate letter, Dr. Nolph has pointed out his concern that very preliminary data from the National Institutes of Health CAPD Registry have been used to demonstrate high drop out rates from CAPD. This data was compiled with very small patient numbers in pilot phases of the Registry. There is no comparable data from hemodialysis populations that are appropriately matched for comparison to this data. It is important also to note that the CAPD Registry includes many newly formed CAPD programs which are initiating this therapy in problem patients. Many centers initiate CAPD on a trial basis to determine if patients are capable of performing CAPD. A trial of CAPD is often utilized as a patient selection technique. Other forms of dialysis are difficult to apply to some patient groups. CAPD is considered to be quite safe, requiring only a short training period. Therefore, a trial of CAPD is considered reasonable. Patient survival on CAPD has been quite good even in the face of new programs beginning this therapy in their problem patients. As an example, two year cumulative survival of 32 patients at the University of Missouri was 85 percent. For 132 patients at the Toronto Western Hospital it was 82 percent, and 81 percent in 20 patients with diabetes mellitus at this same hospital. A preliminary analysis of the CAPD Registry data in the U.S.A. in 381 patients showed a one year cumulative survival of 89.5 percent. References: Peritoneal Dialysis Bulletin, Vol. 1, p. 24, 1981, New England Journal of Medicine, Vol. 306, p. 625, 1982, and CAPD Registry data submitted to the National Institutes of Health, April 1, 1982.)

We have reviewed two year cumulative survivals in chronic hemodialysis patients from the European Dialysis and Transplant Registry. The survival rates were 64.7 percent for the age group 55 to 64. We have mentioned the results in the state of Michigan showing a 54 percent two year cumulative survival. The results of the Missouri Kidney Program Annual Report show a 57.5 percent survival.

Thus, the evidence suggests that CAPD is a safe technique. Most reported deaths have been unrelated to the CAPD technique. CAPD is not associated with many of the life/death risks of hemodialysis mentioned above. Rapid fluctuations of blood pressure are unusual, blood access is not required, rapid changes in body chemistries and sudden arrythmias are not characteristic of CAPD. Neither air embolis nor massive blood loss are a problem.

In summary, CAPD would appear to be a safe technique with a short training period. Many centers prefer to initiate a trial of CAPD in the problem patients. High turn over rates should not be used to condemn CAPD as it does allow patients to try a safe and simple home dialysis technique. Many succeed, as exemplified by the continued growth of the number of patients on CAPD.

It would appear that the medical community does not view the CAPD drop out rates as a detriment to the continued growth of CAPD. Patients continue to elect CAPD and many centers are initiating CAPD programs. The widespread enthusiasm of the medical community is illustrated by the very large number of centers (more than 500) now offering CAPD therapy.

HOSPITAL DAYS

Many studies, including the preliminary data from the CAPD Registry and studies from Canada, suggest that patients on CAPD average 20 to 25 days in the hospital per patient year. Dialysis related complications accounted for only 50.4 percent of these days in the CAPD Registry study. Cardiovascular problems and other medical problems accounted for 42.9 percent. Training days accounted for 6.7 percent. It is likely that the cardiovascular and other medical problems of the patients would have occurred regardless of the dialysis technique used. These patients may have required more hospitalization if these underlying cardiovascular health problems had been aggravated by hemodialysis—a situation which often exists. We suspect that population matched studies would not reveal major differences between CAPD and hemodialysis patients in terms of days in hospital.

Another perspective relates to the question of hospital days. Center hemodialysis patients without complications make contact with nurses and physicians three times per week for a total of 156 times per year. This physician/nurse contact, which is a requisite of center hemodialysis results in many of the extra costs of center hemodialysis which appear as overhead expenses. CAPD patients without complications require medical personnel contact only every 4 to 6 weeks. Thus, 12 visits per year coupled with 25 hospital days would result in 37 contacts with the medical community per year. A better comparison of the cost impact of the two techniques is not in the difference in hospital days (and we even doubt this difference if matched studies were done) but in how many days the patients are leading their own lives free of contact with the expensive medical community. Obviously, such free days enjoyed by the CAPD patient population result in cost savings.

PERITONITIS AND CAPD

One of the major reasons for patients discontinuing CAPD relates to the inability to carry out the technique without contaminating the system. The skills of performing CAPD require motor coordination. Some patients simply do not have that capability. However, peritonitis is usually very responsive to early treatment and results in brief morbidity and an extremely low mortality. The great majority of peritonitis cases are currently treated on an outpatient basis. We anticipate that developments now on the horizon will reduce the risks of peritonitis well below those now observed (1 to 2 episodes per patient year) and this, in turn, will impact markedly on hospitalization days and drop out rates.

THE MEDICAL BENEFITS OF CAPD

Thus far, we have addressed those issues which have been raised to suggest that CAPD will not provide an alternative therapy for large numbers of patients over long periods. We have challenged those allegations. CAPD has striking advantages and we anticipate major long term impact from the delivery of this form of therapy. This impact will demonstrate itself both economically to the government and to the benefit of the patients.

As mentioned, CAPD is a very low risk procedure and is not associated with any sudden death risks of which we are aware. It provides continuous, steady dialysis, very similar to the continuous, physiologic effects of normal kidneys. Rapid fluctuations in blood pressure and body chemistries are absent and this contributes enormously to the feeling of well-being that these patients experience. Patients usually exhibit increased appetite, strength, red blood cell count and ease of blood pressure control. In the diabetic patients, a far better control of blood glucose can be achieved than has previously been possible with any other form of dialysis. Recent studies published in the New England Journal of Medicine suggest that CAPD may give the best results in patients with diabetes mellitus with low mortality rates, low drop out rates and improved rehabilitation. The results in patients with diabetes mellitus so far have been far better than previously reported. CAPD has also allowed dialysis in infants and small children in an acceptable fashion. This was not previously possible. CAPD is, in the opinion of most pediatric nephrologists, the treatment of choice in the pediatric patient awaiting transplantation. If one only considers the pediatric and the diabetic groups, CAPD may be the treatment of choice for up to 30 percent of the ESRD population.

We would reiterate that adequate comparisons between available techniques of drop out rates and survival can not be fairly made in the absence of well matched, controlled trials. Nevertheless, survival rates from multiple reports of CAPD are as good or better than those available on hemodialysis, despite the much mentioned fact that problem patients are frequently placed on CAPD.

It is our hope that issues of reimbursement will not promote brief negative descriptions of those forms of therapy which may not be fiscally advantageous to certain members of the medical community. CAPD, like hemodialysis, is not perfect. There are problems and complications. CAPD does, however, offer many advantages and is clearly a well established, proven form of therapy—and the best form of therapy for a substantial percentage of patients. It is not our contention that it is the best therapy for all patients. It is not our purpose to downgrade hemodialysis or to imply that it is not the most logical choice of therapy for many patients. Until a perfect form of renal replacement therapy is available, we must apply all of the available forms of therapy to meet the special needs of each patient. Hopefully, this will allow the patient to have the freedom to choose that technique which is best suited to his needs and capabilities without undue fiscal restraints.

We would discourage comparisons of CAPD and hemodialysis at the present state of knowledge which attempt to describe one form of therapy as better than the other. Appropriate matched comparisons are not available and most differences probably reflect the influence of other factors such as patient selection rather than differences between techniques. CAPD is undergoing constant improvements and will have dramatically different characteristics in the near future. Data now evolving from the CAPD Registry are still very preliminary with only small numbers available for actuarial analysis. There is no appropriate comparable hemodialysis data.

We hope these comments have been helpful to you as we know you are hearing from many different sources. We hope we speak for those 500 centers which are enthusiastically offering CAPD to their patients. We would be happy to provide additional information as you may require to reach decisions on these critical issues. Please feel free to contact us at any time.

Sincerely,

JACK W. MONCRIEF, M.D.,
Director CAPD Program, Nephrology Division,
Austin Diagnostic Clinic, Austin, Tex.

KARL D. NOLPH, M.D.
Principal Investigator CAPD Registry,
Professor of Medicine, Division of Nephrology,
University of Missouri, Columbia, Mo.

ROBERT P. POPOVICH, Ph. D. P.E.,
Professor Biomedical Engineering,
Department of Chemical Engineering,
University of Texas, Austin, Tex.

W. KEITH PYLE, Ph. D.,
CAPD Registry Director, Department of Chemical Engineering,
University of Texas, Austin, Tex.

Mr. Abbey. With me today is Dr. Jack Moncrief. I have a feeling Mr. Pickle knows him better than I, and if you would like to introduce him, I would be pleased.

Mr. Pickle. I have done that about three times, but I would like to recognize you. You have actually helped invent the process being discussed here, and I have a question or two for Dr. Moncrief later. We would be pleased to hear from you.

Dr. Moncrief. Thank you, Congressman Pickle. Mr. Chairman, Mr. Martin, I appreciate the opportunity to come to talk. The reason I am here is I had understood in a previous committee hearing such as this there had been a substantial degradation and attack made on CAPD and I felt it imperative to make myself available for at least some information that might counter some of those discussions.

Since 1969, I have been involved in caring for patients with end stage reneal disease. When I arrived in Austin, Tex., there was no care in that community, and within the last 35 years we have developed a tertiary medical delivery system which includes a large transplant program, a large home hemodialysis program in which we now have 25 patients, a large in-center program in which we manage 100 patients, and a small hospital program which has only four chairs and manages only acutely ill, non-in-center dialysis patients. And in 1975, with the help of Dr. Robert Popovich, a cosignor of that letter, in a research committee meeting we developed the procedure which is now called continuous ambulatory peritoneal dialysis.

This was simply a response to a single patient's need who was otherwise not going to be served by all of the programs we had developed up until that time. This patient was admitted to the hospital and this program was developed around his need. Within a very short period of time it became obvious to me as a clinician that this patient received very good dialysis from this procedure, which he could not have received otherwise.

We then applied for a National Institutes of Health grant to experiment with three or four additional patients. It also became quickly obvious to me that it was not a fluke. Indeed, we were dealing with a better form of dialysis, and we began to report to the medical community. Our first report was published in 1976 in April. Since that time, many dialysis facilities around the world have adopted this procedure. And as Dr. Nolph expressed, more than 5,000 patients are presently being served by this procedure in the United States.

So I think it is inappropriate for it to be claimed to be an inadequate procedure. Many of these developments have occurred in spite of significant financial disincentives to the home patients, of which CAPD is simply one form. I do not claim CAPD will be the way to do dialysis on the majority of patients because I do not, as the physician for a large number of patients, feel that I can send a large majority of my patients home safely. But I think it is a good form of dialysis therapy. It will serve a population of patients who could not be served with home dialysis otherwise, and I would certainly recommend to the committee that they adopt this procedure.

Mr. Pickle. Dr. Moncrief, for my information and perhaps for Mr. Rangel's and Mr. Martin's, could you give us an explanation of the basic differences between a regular home dialysis treatment and the CAPD treatment which you invented?

Dr. **Moncrief**. Yes; previously, dialysis treatments which included hemodialysis and the other form of peritoneal dialysis called intermittent peritoneal dialysis were done on an intermittent basis. That is, the patient is without kidney function during the interim between the time the medical personnel or the home patient applies the procedure to his body.

CAPD is a much less efficient procedure because we use far less fluid to cleanse the bloodstream of the uremic poisoning. But what that allows is for the patient to carry that water around with him. But it is inefficient, so he must do it all the time. It cannot be done in a dialysis facility because it is continuous. So it is only possible to do it at home, so it is synonymous with home dialysis.

It uses a very small volume of fluid. It is portable. We call it continuous ambulatory which means to walk around, and it is a form of peritoneal dialysis. It is done by the patient and does not require the aid of a spouse or a home health aide, which can be expensive, and it allows the patient to adjust the dialysis procedure to his everyday life rather than having to cram his life into the constraints produced by the previous types of dialysis procedures.

Mr. **Pickle**. As I understand it, if you go to a hospital for dialysis, you have to lie down while receiving the treatment. I have seen patients at your hospital. It takes 30 minutes, an hour or longer.

Dr. **Moncrief**. About 4 to 5 hours.

Mr. **Pickle**. It is an extremely long process. If you are treated in the home, patients give the treatment to themselves or with the aid of a family member or an aide; correct?

But if it is the CAPD treatment, it is a continuous treatment. They can apply it to themselves. They just carry it along with them?

Dr. **Moncrief**. That is correct. So that the patient drains fluid into his abdomen and leaves it for an extended period of time, usually 6 to 8 hours overnight. That fluid removes the uremic poisons from the patient's blood on a gentle basis and that bag is exchanged four times a day. By doing that, the patient does not have the large fluctuations in his physiology which prevents him from having the complications everyone is aware of produced by the high concentrations.

Mr. **Pickle**. I think Dr. Nolph said the blood pressure was stable, the appetite was better. Didn't you also say he gained weight?

Dr. **Nolph**. Many of the patients enjoy the benefits of continuous dialysis. Many have problems with intermittent dialysis because it is so efficient and quick that rapid changes occur, rapid fluctuations in blood pressure, and many enjoy the benefits of the continuous.

Now, CAPD is not the preferred therapy for all patients. I would not say that. But many have done better, prefer it and would not change back.

Mr. **Pickle**. Dr. Moncrief, one more question. What would be the effect of the proposed change in physician reimbursements on the CAPD program?

Dr. **Moncrief**. At present, the physicians reimbursement is at one level and the proposed reimbursement is a substantial decrease in the total physician reimbursement. So I think there will be generally a disincentive for physicians to participate in depth in the management of patients because they will be paid less, approximately 20 or 30 percent depending upon their mix of home patients. So I think there is a decrease in the physician reimbursement that will have some disincentive to the physician.

However, the facilities are to be paid for the first time for the out-patient management of home dialysis patients. Previously, the facilities received no funds. Once they trained the patients and sent them home, their facilities received no funds.

Now, by the new regulations they will receive substantial sums of money for managing those patients at home and, in fact, will receive the funds to make up for the losses of their in-center dialysis funds. So there is a counterbalancing weight.

Mr. **Pickle**. How are the facilities reimbursed which have the CAPD patients now?

Dr. **Moncrief**. They are reimbursed during the training period, approximately $150 per day during the training session, which allows 10 days to 2 weeks. After that the facilities are not reimbursed at all. So there is no payment to the facility except when a patient actually comes into contact to pay for the physical contact with the patient. No management and availability of personnel is paid by HFCA at this time.

Mr. **Pickle**. I thank you, Mr. Chairman.

I want to say again that I have been in Dr. Moncrief's hospital. I have seen the CAPD treatment that he and Dr. Popovich initiated, and I commend their achievements.

Chairman **Rangel**. Are there any side effects from this?

Dr. **Moncrief**. Certainly, there are side effects to almost every substantial medical treatment. The biggest side effect to CAPD is if the patient contaminates the exchange, he can get an infection of the abdomen called peritonitis. That is a risk.

However, in my almost 6 years of managing patients, and I have now managed about 100 patients in CAPD, I have had one patient die. I have had many who have peritonitis, but I have only had one patient die from peritonitis. That was an 80-year-old female who ruptured her colon and spilled fecal content into her abdominal cavity and died rapidly. I am not sure that was related to the procedure. I am sure she would have died had she not been on CAPD.

So it is a very minor mortality risk. It is a substantial morbidity risk. And for that reason it will not be a procedure for everyone. The patients must want to do the procedure badly enough to be careful not to contaminate themselves. And everyone is not like that. And we cannot expect CAPD or any form of home dialysis to be done by people simply not interested in caring for themselves.

Chairman **Rangel**. You say it is less expensive. What actually besides medical direction and medical advice, what paraphernalia is used for that?

Dr. **Moncrief**. Four times a day the patient must infuse from his abdomen the fluid residing there and replace that with two quarts of fresh fluid that is provided by a manufacturer. It has expenses attached to it.

Chairman **Rangel**. How much is it?

Dr. **Moncrief**. It costs $8.35 per exchange, four times per day.

Chairman **Rangel**. How much is the bag?

Dr. **Moncrief**. That varies depending upon many factors, but it is somewhere around $7.50, with certain contracts and discounts.

Chairman **Rangel**. Is that it? Is that the cost?

Dr. **Moncrief**. That is the paraphernalia cost.

Chairman **Rangel**. That is what I meant.

Mr. Martin, would you chair this meeting for us while we go to another meeting?

Mr. **Martin**. I would just be honored, Mr. Chairman. I will not be long. [Laughter.]

Chairman **Rangel**. Thank you all.

Mr. **Martin**. Dr. Moncrief and Dr. Nolph, both of you have given a yeoman response to the earlier testimony of Mr. McPhelley, who was here representing National Medical Care, Inc., of Boston. I am curious. Do you know whether they use CAPD?

Dr. **Nolph**. It is my understanding they do provide CAPD therapy in a number of their centers.

Mr. **Martin**. They use it, and yet they——

Dr. **Nolph**. It is my understanding they are using it in an increasing fashion.

Mr. **Martin**. So it is available to them?

Dr. **Nolph**. Oh, yes. They are providing this form of therapy to many of their patients.

Mr. **Martin**. Your defense told us all so much about a good thing that it does raise a question about the cost. You have indicated it is about $105 a day.

And in your testimony, Mr. Abbey, you say it is $105 per treatment?

Mr. **Abbey**. In dealing with the cost of CAPD we have to keep in mind it is a form of treatment which goes on continuously. So whereas you can talk in terms of per-treatment for hemodyalysis, you have to make some translation on a time basis for CAPD.

As I have indicated in my testimony, when we translate CAPD costs to the same basis as hemodyalysis, which is three treatments per week, the equivalent figure is, as you suggested, about $105 per treatment.

Mr. **Martin**. $105 equivalent to three times a week.

Mr. **Abbey**. So home weekly costs would be around $315.

Mr. **Martin**. Even though you are actually making four a day?

Mr. **Abbey**. Yes, 28 exchanges.

Mr. **Martin**. Twenty eight exchanges a week, yes. I am not sure whether that makes everything clearer to me or not. But that does come out to be more expensive than home hemodyalysis.

Mr. **Abbey**. Yes; it does.

Mr. **Martin**. And yet it does not involve the expensive equipment. Is the expensive equipment amortized in the home dialysis cost of $97?

Mr. **Abbey**. Many figures are available as to the cost of home hemodyalisis. The difference lies, I think, in accommodating for the hardware, how high the lease payment is or, if purchased, how fast the purchase price is amortized.

Also, of course, there is a difference as to whether there is a paid aide or whether the patient's spouse assists him.

Mr. **Simmons**. Mr. Martin, may I respond to that?

Mr. MARTIN. Let me pursue this for just a moment, or my mind will cloud up on me in a moment, if it has not done so already.

As I estimate, then, $315 per week for CAPD, about $230 of that is the cost for fluids, which you say were $8.35 a package?

Mr. ABBEY. I have not computed this. Dr. Moncrief is correct. All of the supplies for an exchange cost approximately $8.30.

Mr. MARTIN. Times 4 times 7 would be about $230, would it not?

[Mr. Abbey nods affirmatively.]

Mr. ABBEY. Attached to my testimony is an exhibit which shows the breakdown of the other costs as we perceive them.

Mr. MARTIN. Would there be any reason for this treatment to cost more than home hemodialysis, or should it cost less? I know I am intruding into private enterprise.

Mr. ABBEY. I think it probably costs about the same. As I said, there are variables in the treatment of the hardware and the home system.

Mr. MARTIN. You still have to own, maintain, and operate hardware at your plant and then ship the packets out.

Mr. ABBEY. There is no hardware involved in CAPD.

Mr. MARTIN. At your plant there is none?

Mr. ABBEY. Well, we manufacture it.

Mr. MARTIN. Well, that is hardware. It is internalized in your plant rather than——

Mr. ABBEY. That is true. It performs the manufacturing function.

Mr. MARTIN. You do not take clear North Carolina brook water and ship it out to them.

Mr. ABBEY. We could, but the FDA might have some thoughts on that. [Laughter.]

Mr. MARTIN. Mr. Simmons.

Mr. SIMMONS. Mr. Martin, I feel like a balanced response would help your question. I am administrator of a dialysis facility, and we have 50 percent of our patients on home dialysis. About 40 percent of those are on CAPD and 60 percent on hemodialysis. Travenal has been marketing that product to the medicare program at $11.34, and to providers they market it for $7.32.

Now that a second company is on the market—there is no reason to suggest it—but now that there is a second company on the market, we are seeing the cost of CAPD solutions coming down precipitously 14.6 percent. HFCA's data suggest that it is $114 equivalent cost for CAPD versus $97. That $97 did not include a paid aide.

It is our opinion that now that a second company is in the business and there will not be this gross profiteering that has been going on over the last 2 years——

Mr. MARTIN. Gross profiteering?

Mr. SIMMONS. Gross profiteering.

Mr. MARTIN. By him. Not by you; right?

Mr. SIMMONS. Not by me, unfortunately. [Laughter.]

I think it will be cheaper than hemodialysis at home, no question about it.

Mr. MARTIN. That is usually the pattern that follows with all new developments, is it not?

Mr. SIMMONS. Unfortunately, yes.

Mr. MARTIN. With electronics and others.

Mr. **Simmons**. Yes. But normally, the Government does not pay that sole manufacturer.

Mr. **Martin**. That is the reason I raised the question. If it were just for convenience, certainly you would expect, as Dr. Nolph pointed out, that many patients would choose that convenience. If they did not have the able partner at home that would be necessary for home hemodialysis, there would be many who would, for convenience, prefer it.

You said they would rather die than switch. If it were just an additional charge, while it might be justifiable for the patient to pay, it would not necessarily be justifiable for the taxpayer to pay more for that convenience. That is why I was inquiring as to the basis of the cost. But if there are competitive factors that would develop after a period of time, then you would expect those to begin to equalize the market. And that is essentially what you expressed a hope for, is it not, Mr. Simmons?

Mr. **Simmons**. Yes.

Mr. **Abbey**. I do not think this is the proper forum for Mr. Simmons and me to argue about what my company charges. But I would like the record to show that his facts are inaccurate.

[The following was subsequently received:]

Additional Testimony of G. Marshall Abbey, Vice President, Baxter Travenol Laboratories, Inc.

During the April 22 hearings before the Subcommittee, Mr. Simmons of El Camino Dialysis Services raised questions concerning the manner in which Travenol bills Medicare for CAPD supplies. Travenol would like to take this opportunity to set the record straight on this question.

First, it is not Travenol's policy to charge list prices (e.g. $11.34 per Dianeal bag) to Medicare. Second, Travenol did not charge high prices initially and lower prices when competition developed.

Effective December 17, 1980, the pricing policy for basic CAPD supplies sold to patients who have assigned their benefits from Medicare to Travenol has been:

Solutions: 34 percent discount off Travenol low list prices.

Prep Kits: 50 percent discount off low list price for the Model 1 prep kit (35 percent discount off low list price for the Model 2 prep kit containing Betadine brand antiseptic rather than generic providone-iodine).

Travenol list prices have remained constant since 1980. For the highest volume codes, this policy results in a price of $7.32 for solutions and $1.00 for prep kits. Prices differ slightly for different solution sizes and dextrose concentrations and if the Model 2 prep kit is used. Also, prices to some customers are higher than those available to Medicare. Although for convenience Travenol bills for CAPD supplies on a per unit basis, the product supplied is more than just a bag. Included in the $8.32 price is a spectrum of Travenol services including inside home delivery, patient and staff training materials and support, inventory management, and continued technological enhancement to the Travenol CAPD system.

This pricing policy is consistent with our overall cost estimate of $13,000 in annual supply costs, based on $12,000 in basic supplies at $8.32 per basic exchange and, on average, $1,000 per year in additional costs for differing bag sizes, additional ancillaries, etc. These additional costs of course vary from patient to patient.

Prior to December, 1980 Travenol provided CAPD supplies to Medicare patients under a more complicated, manually billed system involving discounts for the purchase of CAPD supply kits consisting of solutions and prep kits. Although pricing varied considerably from order to order depending upon whether the balanced supply kit was ordered or just solutions, the average price was approximately the same as the $8.32 exchange. The change in December, 1980 was designed to simplify pricing, not to increase revenues.

In summary Travenol rejects the allegation that the Company has billed Medicare under assignments of benefits for CAPD supplies at prices other than as outlined above.

Mr. **Martin**. Dr. Freeman, did you wish to comment on this discussion?

Dr. **Richard B. Freeman**. Yes, sir.

Mr. **Martin**. Please go ahead.

Dr. **Richard B. Freeman**. As a physician, let me comment not on the industrial competition aspect. I believe a degree of balance is necessary. Speaking from the standpoint of the Renal Physicians Association, representative of the entire group, you have present here two of the three world authorities on chronic ambulatory peritoneal dialysis.

And I think if you would poll people who have been involved in the end-stage renal disease program from its inception in 1960—that is, the treatment program—and the 1973 program, there would be a balance of advocates for hemodialysis or chronic ambulatory peritoneal dialysis.

Since the data is not in, as described by Dr. Nolph, it is not yet an accepted part of the armantarium throughout the country with which we deal with end-stage renal patients. It is an interesting innovation which deserves further study. It is probably out of the experimental phase, but there needs to be more data proved regarding its efficacy and long-term effects.

In some institutions the infection rate is rather incredible. People must learn how to do it. People have learned how to do hemodialysis and how to do transplants.

Mr. **Martin**. That sort of learning curve is typical with the medical profession, in general, is it not?

Dr. **Richard B. Freeman**. Yes. But there are fads also that occur in the profession. Earlier treatments for coronary artery disease, surgical procedures have come and gone.

Mr. **Martin**. Would you say that the figure of 40 percent CAPD and 60 percent hemodialysis is about the breakdown?

Dr. **Richard B. Freeman**. No. It is hard to get 40 percent of all patients. A target rate, to get 40 percent of all patients home, is a good rate to shoot for whichever method of therapy one chooses, home hemodialysis, home peritoneal dialysis, or whatever it is suited for.

If I may comment, a point that has not been touched all day today. Sitting on your beautiful beaches in North Carolina, one ponders these regulations, and I have done so in the last few days. The consumer, the client referred to by Mr. Rangel, the patient has the option to gain information on all of these modalities of therapy. And when explained to them, of course, they will choose one which will keep them alive. But they must be educated as to the potential side effects, the risk factors, and the inconveniences.

We as physicians are obligated to do this. Indeed, under law, we are obligated to do this. So the patient is a significant actor in this whole scene as well. And just to finalize that through, one of our problems with the regulations which I had hoped to mention was it is possible that these regulations would impair significantly the transplantation program that Dr. Cerilli talked about ealier.

I do not agree with some of his other statements, but it would significantly impair this, which is an advancing modality wherein I think we see the first breakthroughs in controlling the rejection reaction. It will be 10 years or so until they are effective. But they are coming through in research.

Mr. MARTIN. Is that developed adequately in your testimony, or should I ask you to explain further about its impairment of transplant technology?

I will ask unanimous consent, if you will provide me with a 2- or 3-page summary further elaborating on that, we will have it made a part of the record.

Dr. Nolph.

Dr. NOLPH. I would like to endorse Dr. Freeman's call for a continuing evaluation of CAPD. But I would also like to call for a continuing evaluation of all of the forms of therapy we provide.

Mr. MARTIN. I notice he is nodding his head in agreement.

Dr. NOLPH. CAPD now has a funded registery. So we are learning about CAPD. And as we gather that data we will know more and more about CAPD. The hemodialysis registry folded years ago. So we will have CAPD data, but no adequate hemodialysis data with which to compare it.

Hemodialysis data gathered years ago was gathered when patients were mainly younger, and many studies show that the mean age of the dialysis population is shifting higher and higher all of the time. We are now taking the diabetics, the patients with cardiovascular disease.

This is why it is so misleading to look at CAPD dropout rates and hospitalization rates and compare them with hemodialysis data 10 years old or from a different continent, not age-matched for all of these population features which probably influence outcome.

Hemodialysis is not a gold standard, in my point of view. It also has its problems, such as blood access, air embolis, sudden changes in blood pressure which precedes stroke, myocardial infarction, et cetera. And I think these deserve continuing interest as well.

Mr. MARTIN. Dr. Freeman, in your testimony, in addition to your prepared testimony, you were discussing the difference between stable patients who can go to any facility, and many of whom can go to home dialysis, and instable patients such as those with hypertension or diabetes, or as I believe Dr. Thompson has indicated, who just misbehave. These require more attention, more expenses for the hospital, and complications.

Is there a wide range of costs here? I assume there is.

Dr. RICHARD B. FREEMAN. Yes, an extremely wide range of costs. And I would emphasize these are only a small number of facilities, of hospitals, primarily tertiary care centers. The wide range of costs could go as high as $350 to $400 per day because these people may be cared for in intensive care units.

Mr. MARTIN. The reason I was getting into this, I wondered whether it would be better, in your opinion, to raise the rate that is allowed for everybody regardless of how many of these instable dialysis patients they have, or would it be better to try to incorporate a factor that relates to the ratio of unstable patients that they do have and try to take it into account on a case-by-case basis?

As I understand, that is what the provision for exceptions is, to allow those who petition for a higher allowance, to allow for those to come in and present their evidence as to how many patients they have, what the actual expenses are, and what the procedures are.

Dr. **Richard B. Freeman**. Our strong recommendation is that the hospitals that have received exceptions now be reviewed and these exceptions be denied unless the hospital can demonstrate that their true costs are higher and that they are treating an atypical patient mix.

It is our opinion that significant cost savings could be accrued by that process. But there are hospitals that perform routine maintenance to stable patients who have exceptions, and we believe this is not proper.

Mr. **Martin**. But certainly you should not keep the rate up high for those facilities who decline to take unstable patients; should you?

Dr. **Richard B. Freeman**. That is correct.

[The following was subsequently received:]

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Nephrology Unit
Department of Medicine

April 28, 1982

The Honorable Charles B. Rangel
U.S. House of Representatives
2432 Rayburn House Office Bldg
Washington, D.C. 20515

RECEIVED
MAY 4 1982
Ways and Means
Subcommittee on Oversight

Dear Mr. Rangel:

I wish to congratulate you on the conduct of the Hearings regarding the proposed rule makings for the ESRD program. Your depth of knowledge, skill in perceiving nuances of a difficult and complex program and your good humor provided a very encouraging day for those of us with significant concerns over the ESRD program. The points that you developed through those who testified should have made a significant impact on the Health Care Financing Administration. I sincerely hope this will be the case.

During the final panel of the Hearings Mr. Martin became interested in a statement I made about the potential impact of the proposed rules on treatment modalities other than home dialysis. I wish to make it clear that the Renal Physicians Association, for whom I speak, encourages home hemodialysis and transplantation as preferred methods of treatment for patients with renal failure. However, we have the exact concerns that you drew out in the Hearings regarding the potentials for restricted access to care and a decrease in surveillance of patients in hospitals and patients with psychosocial or medical complications. Certainly, the point made about the children was very important.

I am enclosing a written statement that I have sent to Mr. Martin about a question that he requested further elaboration and discussion. This was done when you were speaking with Dr. Biagg.

Together with Dr. Biagg and other members of the Renal Physicians Association we are grateful for your interest and if we can provide any type of input for more reasonable regulations, we will be ready and willing to do so at your request.

Again, thank you for your interest and action in this area.

Respectfully yours,

Richard B. Freeman

Richard B. Freeman, M.D.
Head, Nephrology Unit
President, RPA

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ADDENDUM TO THE STATEMENT OF THE RENAL PHYSICIANS ASSOCIATION BEFORE THE SUBCOMMITTEE ON OVERSIGHT COMMITTEE ON WAYS AND MEANS ON PROPOSED RULE MAKINGS OF FEBRUARY 12, 1982

PRESENTED ON APRIL 22, 1982

RICHARD B. FREEMAN, M.D.
PRESIDENT

This statement is in response to the request of the Acting Chairman, Mr. Martin, to comment on the potential impact of the new proposed rule makings on transplantation and other treatment modalities in the End Stage Renal Disease Program (ESRD). The request was made during the discussion of the final panel at the hearings of the Subcommittee on Oversight, Committee on Ways and Means on April 22, 1982 and was to be entered as part of the record.

The Renal Physicians Association (RPA) has taken the position that home hemodialysis and transplantation are preferred methods of treatment for patients with renal failure. Chronic ambulatory peritoneal dialysis (CAPD) is a relatively new modality of therapy but more experience is required before this therapy can be designated as a preferred method of home treatment. At the present time CAPD is more expensive than home hemodialysis and is counter to the consensus that cost containment is a high priority in the program.

In-center hemodialysis is necessary for patients with psychosocial or medical problems that preclude home training or transplantation. This group of patients can be subdivided into "stable" and "unstable" patients. Stable patients are treated in-center, either free-standing or hospital based units. There should be very little difference in reimbursement for treatments in these stable patients except in so far as allowable medicare costs are higher in hospital units. A proportion of the entire ESRD population are unstable patients (perhaps 15-30%) and require more sophisticated treatment and closer surveillance. This requires a broad expertise of personnel and equipment that is available only in hospitals.

The new proposed rule makings attempt to provide incentives for the physician to urge patients to accept home hemodialysis for therapy. Practically all patients with renal failure are referred to internists-nephrologists for care. The nephrologist and his/her supporting team evaluate each patient and advise the patient as to which modality of therapy is best for each individual. The conflict arises in the very stable uncomplicated patients because these are the best candidates for home dialysis and for transplantation. The present proposed rules attempt to provide financial incentives for encouraging home dialysis. If physicians are placed in the untenable position to derive maximum reimbursement to maintain their total program, e.g. apply proceeds from home patients to cover inadequate reimbursement for in-center patients, they are likely to do so despite the agonizing compromise in their judgment as to what is best for each individual patient. They may not refer patients for transplantation for which the nephrologist is not reimbursed. Thus, treatment options for ESRD patients will be restricted.

Though the RPA believes the vast majority of physicians make decisions based on what is best for each individual patient, the proposed rules will force physicians to make decisions to maintain the viability of their entire program. Previous statues and regulations require that patients be given the full range of treatment options. The Renal Physicians Association supports this concept. However, when one's program is jeopardized by economic constraints, the physician will operate in the manner that will maintain economic viability and the capability to deliver treatment of some sort to all patients in need. Unfortunately, we predict that economic constraints will result in a decrease in referral of patients for transplantation.

Finally, the restrictive nature of the exception process which will reduce facility and physician reimbursement will decrease the capability of hospital based units to maintain dialysis facilities necessary to support an active transplant program.

The position of the RPA is that the spectrum of treatments necessary to sustain an integrated program that offers all types of therapy must be maintained. Incentives that encourage only one type of preferred treatment will decrease the numbers of patients who will receive other types of preferred or necessary treatment. Indeed, the proposed rules reduce reimbursements for therapy other than home dialysis and will result in counterincentives for recommending the remaining spectrum of treatments available.

Mr. MARTIN. Well, I am sure there are many other words to be said on this subject. But you have all given this your best shot, and we appreciate it. And others have come to testify on other occasions. Thank you again.

This concludes the hearing for the day.

[Whereupon, at 4:30 p.m., the hearing was adjourned.]

[The following was submitted for the record:]

STATEMENT OF THE U.S. GENERAL ACCOUNTING OFFICE

This statement focuses on the data used by the Health Care Financing Administration (HCFA) in preparing its recent proposal to establish a prospective reimbursement system to pay for home and outpatient dialysis treatments under the ESRD program. The statement also provides some information on physician compensation in the ESRD program where the related costs are generally reflected in the prospective payment rates and briefly discusses the role of ESRD networks in administering the program.

In summary, we believe that the data HCFA used, and the resulting proposed ESRD payment rates, probably overstate what it would cost an efficient and economical provider to deliver needed services. In particular, we question the accuracy of the cost data obtained on independent ESRD facilities because of the incomplete audits on which the data is based.

Specifically: The 13 facilities we reviewed reported $15.4 million in costs, including about $6 million in related organization transactions that had not been adequately examined to eliminate intercompany profits and other unallowable costs;

Physicians' compensation for administrative services and profit sharing arrangements were included in the audited costs without assessing their reasonableness. The annual payments we were able to identify ranged as high as $360,000 per facility in addition to whatever the physicians received from Medicare for providing ESRD medical services.

BACKGROUND

The Social Security Amendments of 1972 (Public Law 92-603) provided Medicare coverage to persons suffering from kidney (renal) failure who are either currently or fully insured under the Social Security Act or are dependents of a person currently of fully insured. The program that resulted from this provision is known as the ESRD program. The program is generally considered effective in protecting beneficiaries from the catastrophic costs associated with caring for a person with renal failure. However, the large and rapidly rising costs of the program—from about $230 million in 1974 to an estimated $1.8 billion in fiscal year 1982—have caused great concern about the future of the program.

In 1978, the Congress passed amendments to the ESRD program (Public Law 95-292) designed to encourage patients to dialyze at home which was believed to be less costly. These included (1) a prospective reimbursement system for home dialysis based on paying facilities a target rate; and (2) 100 percent reimbursement to facilities for equipment to be used and maintained for home patients. The original objectives of our work were to evaluate the reasonableness of the target rates that had been established and the effectiveness of the new provisions in encouraging patients to dialyze at home. However, when the Congress provided, in the Omnibus Budget Reconciliation Act of 1981 (Public Law 97-35) for establishing new methods of paying for ESRD services, we began reanalyzing the data gathered in light of these revisions.

We reviewed the audits conducted by Medicare intermediaries for 13 independent facilities and HCFA's adjustments to these audits to determine the reliability of the resulting data. Our analysis of the audits consisted primarily of a review of the audit reports for the cost reporting years ended in 1978 or 1979 and supporting working papers prepared by the auditors. We also reviewed the adjustments made by HCFA and the supporting documentation for the adjustments. In addition, we talked or met with the intermediary auditors and HCFA officials to obtain additional information on the work performed. Our proposed adjustments were discussed with the intermediary auditors.

Our cost data for home dialysis is based on the costs incurred in 1980 for a sample of 656 beneficiaries dialyzing at home as of December 31, 1980. Our sample was drawn from all the home patients residing in 13 States and while the data is representative of these States it cannot be projected to the Nation. We obtained data from all the Medicare claims processing contractors that we could identify as having paid for services provided to our sample beneficiaries. This involved obtaining data from 27 carriers that pay for Medicare part B services such as physicians' services and dialysis equipment and supplies and 21 intermediaries which pay facility based suppliers such as hospitals and independent renal dialysis facilities.

There are two general types of dialysis treatment modes, hemodialysis and peritoneal dialysis, both of which can be performed at home. For hemodialysis, the most widely used mode, blood is taken from the patient's body and passed through a dialysis machine, which filters out body waste before returning the blood to the patient. Under peritoneal dialysis the blood is filtered within the patient's abdominal cavity without leaving the body. There are three variations of peritoneal dialysis—continuous ambulatory (CAPD), intermittent (IPD), or continuous cycling (CCPD). Of the three variations, CAPD has gained popularity. Our review covered patients using each mode of treatment.

HCFA data shows that overall about 17 percent of ESRD beneficiaries dialyze at home. Of those beneficiaries associated with independent facilities about 10 percent dialyze at home and of those associated with hospitals about 23 percent dialyze at home.

HCFA'S PROPOSED REIMBURSEMENT SYSTEM

On February 12, 1982, HCFA published a proposed rule to change the way Medicare pays for outpatient dialysis and related physician and laboratory services. Under this rule, HCFA proposes to establish a composite rate designed to cover the costs of both home and in facility dialysis treatments. A simplified explanation of the composite rate is that it is made up of HCFA's estimated home dialysis costs times the percentage of all ERSD beneficiaries who dialyze at home plus HCFA's estimate of in facility dialysis costs times the percentage of beneficiaries dialyzing in facilities. Each facility will receive a certain payment rate per treatment, adjusted for geographic differences in the cost of labor. According to the proposal the average payment for independent facilities would be $128 per treatment and $132 per treatment for hospital-based facilities. These amounts will be paid regardless of whether the treatment is furnished in the facility or in the patient's home. The proposal would do away with the home target rates and the 100 percent equipment reimbursement payment methods established pursuant to the 1978 amendments. The methods currently used to reimburse physicians for routine support services would also be changed in a manner which HCFA believes will eliminate some of the economic incentives for physicians to treat dialysis patients in the facilities rather than at home.

INDEPENDENT FACILITY AUDITS WERE POORLY DONE

HCFA has proposed the establishment of a prospective reimbursement system to pay for dialysis services in the patient's home and in facilities. We believe that prospective payment systems should be based on the costs which would be incurred by an efficient and economical provider to deliver needed services. In fact, the Congress has required the States to have Medicaid reimbursement systems for hospitals and nursing homes which meet a similar criteria.

In order to determine the level at which efficient and economical providers can deliver needed services, we believe it is necessary to obtain through audit, data on actual reasonable and allowable costs incurred by a statistically valid sample of providers. To see if HCFA had this data, we reviewed 13 of the 38 audits of independent facility costs which the intermediaries had performed and HCFA used in establishing its proposed rates. We do not believe the audits provide HCFA with the data necessary to adequately establish a prospective reimbursement system because the audits did not result in the elimination from the costs reported by the facilities substantial amounts of unreasonable and unallowable costs.

The total costs reported by the 13 facilities were about $15.4 million. Work done by the fiscal intermediaries and HCFA resulted in reductions of about $2 million to the reported costs. Based on our limited review, we estimated that there should have been additional reductions of about $700,000. The adjustments we made would reduce the average cost per treatment for the 13 facilities reviewed by about $5.50. In addition, we believe there are significant amounts of unallowable or unreasonable costs of related organization transactions which should have been eliminated from the facilities' reported costs. However, due to the limited review work done on related organization transactions by the intermediary auditors, we could not determine from the data reviewed how much these adjustments should have been. A more complete audit could have resulted in additional reductions.

Attachment I summarizes the costs and number of treatments for the 13 facilities as reported by them and the adjustments made by the intermediary auditors, HCFA, and GAO. Most of the reductions we made related to: incorrect allocations of parent company home office and/or regional office expenses; insufficient documentation to support management fees charged by related organizations; the cost of dialysis treatments provided for patients of other facilities for which those facilities were responsible; nonrecurring and/or undocumented legal expenses; and profits on transactions between related organizations.

We made reductions on all of the audits reviewed. Some examples of unreasonable and unallowable costs we identified which neither the intermediary nor HCFA had identified are:

A facility paid its parent company $28,212 for management services but we saw no evidence that any services had been provided;

One facility included $29,065 in costs for services provided to hospitalized patients. The hospitals were billed for these services and the hospital can include these charges in its costs for medicare reimbursement purposes. Permitting the facility to include these costs would amount to duplicate payment—once to the facility and once to the hospital. Several other facilities also included the same type of costs;

A facility owner was paid $11,856 in excess salary; and

A facility paid a related organization $5,430 more to sublease a building than the related organization paid to lease it.

Some of the intermediary auditors were more successful than others in identifying unallowable costs, however, we generally found similar deficiencies in the audits performed by each of the five intermediaries whose auditss we reviewed. These five intermediaries performed 23 of the 38 independent facility audits.

Perhaps of more interest than the unallowable costs we were able to identify by reviewing the intermediaries' workpapers were the questionable costs where the documentation in the workpapers was insufficient for us to determine how much cost should be eliminated. Most of these costs related to transactions between 12 of the facilities and organizations which we considered related to the facility by common ownership or control. Medicare cost reimbursement principles permit reimbursement for such transactions at the lower of (1) the cost incurred by the related organization in furnishing the supplies or services or (2) the costs at which the supplies or services could be obtained elsewhere (see 42 CFR 405.427). About 60 percent of the related organization transactions were for purchases of supplies, and the remainder were primarily for management and administrative services. The costs of these supplies and services in most cases amounted to more than 40 percent of the facilities' total reported costs. Attachment II summarizes the total costs reported by the facilities and shows our estimate of the portion of the costs represented by related organization transactions. Examples of these related organization transactions are:

A facility purchased $413,539 worth of supplies from a related organization. The related organization was not audited and no adjustments were made to eliminate any profits or unallowable costs;

Another facility purchased $1.6 million worth of supplies and services from a related organization. This facility routinely marked-up supplies provided to home patients. In 1978, the markup was 10 percent (increased to 35 percent in 1981). Any intercompany profits or unallowable costs were not eliminated because the related organization was not audited; and

A facility was allocated $101,790 for services provided by the regional office of the parent company, a chain organization. The auditors eliminated $4,322 of this amount based on an error in the amount allocated. The remaining $97,468 was unaudited.

The data reviewed did not provide enough information to enable us to determine how much of the related organization costs were audited by the fiscal intermediaries. However, none of the audits determined the actual costs to the related organizations selling dialysis supplies or the costs at which the supplies could be obtained from nonrelated organizations. Also, in many instances, home office and regional office costs reported by chain facilities were not audited. Therefore, substantial portions of costs were included in the cost reports HCFA used without adequate assurance of compliance with Medicare regulations concerning related organization costs.

We did obtain some information which indicates the extent of unallowable or unreasonable costs included in some related organization transactions. One facility covered by our review which belonged to a large national chain and related organization costs of about $540,400, including home office expenses of about $124,400. This amount was part of about $10.3 million in home office expenses the parent company allocated to its ESRD facilities for the year. HCFA designated a separate intermediary to audit the parent company home office costs. As part of our analysis, we reviewed the report and related working papers for this audit and found the audit to be insufficient.

We discussed this audit with intermediary officials. One of the officials advised us that no effort had been made to determine if the home office costs were reasonable or if the costs were related to patient care. He advised us also that HCFA had not authorized enough time to conduct an adequate audit and they only eliminated the obvious costs which were specifically unallowable under Medicare regulations. For most of the $10.3 million home office expenses the auditors simply verified that the amounts reported agreed with the amounts shown in the parent company's general ledger. We believe that this home office expense audit cannot reasonably be used to determine the cost of dialysis treatments. Five of the 13 facilities whose audits we reviewed were part of this chain. All had essentially the same arrangements with related organizations.

The Inspector General's Office for the Department of Health and Human Services recently completed a review of the 1977 and 1978 costs reported by one of the facilities in this chain. Their review showed that:

This facility had paid about $309,000 or 149 percent more for property and equipment leased from a related organization than it would have cost to own the same property and equipment;

The facility was charged 22 percent more by a related supply company for certain routine dialysis supplies than the related organization had charged three unrelated facilities in the same geographical area; and

In some instances, the facility paid up to 56 percent more for supplies purchased from the related organization than would have been paid had the supplies been purchased from unrelated vendors.

Another facility which is part of another chain paid a related organization about $199,300 for dialysis supplies which amounted to about 39 percent of the facility's total operating costs. Unlike most of the audits we reviewed, the intermediary auditors for the facility tried to eliminate the related organization profits for these transactions based on a profit percentage computed from the related organization's unaudited financial statements. Intermediary officials told us that their $32,735 adjustment did not eliminate all profits involved, but it was the best adjustment they could do since the related organizations would not allow them to review pertinent invoices.

The related organization that provided the dialysis supplies to the facility reviewed, held the master lease on the facility, and owned the facility's dialysis machines. We believe that a full audit of this organization's costs probably would have disclosed significant amounts that were unreasonable or not related to patient care. For example, we noted that in 1979, the organization spent $163,000 for five Mercedes Benz sports cars—one for use by each of the five physician owners.

In addition, this related organization was managed and operated by employees of four of the ESRD facilities controlled by the owners of the related organizations which had no employees of its own. The organization paid the facilities $36,000 for the services of these employees. The intermediary auditors eliminated $36,000 from the facilities' cost report based on the amount of time that the facility employees stated was devoted to operating the related organization. The intermediary auditors told us that they believed the adjustment was reasonable since it equaled the amount paid. We believe that the true cost of operating the supply and leasing business could have been significantly more than the $36,000 eliminated and should have been audited. There was not enough information available for us to determine the actual expenses incurred by the facilities to operate the related organizations.

We are presenting this information to provide a general idea of the extent of related organization transactions. The HCFA audits generally did not eliminate related organizations' profits or unallowable costs. Intermediary officials told us that they were not provided enough time of financial resources to audit the cost of related organizations. We believe that the audits should have been expanded to include reviews of related organizations' activities so that unallowable profits and costs not related to patient care could have been identified and eliminated. The audits should also have included some market surveys to determine the costs that the goods and services could have been obtained from unrelated organizations. Since such review procedures were not followed we question whether the audit results should be used as the primary basis for establishing prospective reimbursement rates.

PHYSICIAN COMPENSATION

As part of our analysis of the 13 facility audits we obtained some information on the amount of compensation and other benefits several physicians receive through the ESRD program. Medicare regulations allow physicians to select one of two reimbursement methods for their ESRD services, the initial and the alternative methods. Under the initial method, reimbursement for physicians' routine supervisory patient care is made to the facility as part of the facility's reimbursement rate. The facility then reimburses the physician for his/her services. Non-routine services are billed separately and paid on a fee-for-service basis. Physician services provided to home patients are billed on a fee-for-service basis. Under the alternative reimbursement method, the physicians are paid a comprehensive monthly fee by Medicare for supervisory services provided to both in facility and home patients. HCFA has set a maximum reimbursement rate for services provided to in facility patients at $260 per month and $182 per month for home patients. Each carrier establishes monthly reimbursement rates for the physician in its service area subject to the limits set by HCFA. Under HCFA's proposal, all physicians would be paid under the alternative method and would be paid the same amount for infacility and home patients—an average of about $18[illegible] per month per patient.

Although there are some limits on the amount Medicare will reimburse for some ESRD services, there is no overall limit on the amount of compensation, benefits, or profits that physicians can receive under the ESRD program. Some of the information we were able to obtain on physicians' compensation and other benefits shows that some physicians received significant amounts of compensation or monetary benefits through the ESRD program. Generally, payments to physicians for administrative services and profits would be included in the facility cost reports. Some examples follow.

The physician owner of a relatively small ESRD facility received about $96,000 in a 1-year period from the facility for administrative services, even though the facility had a non-physician administrator, an assistant administrator, and a chief of nursing services. During the same period, the physician received about $57,400 from the Medicare program under the alternative reimbursement method. The physician also sub-leased the building to the facility and received dividends as its majority stockholder. In addition, the physician maintained a full-time medical practice from which he received Medicare payments of about $44,500 for non-ESRD services.

Two owner physicians of another facility received during a 1-year period combined compensation of: $192,000 from the facility for administrative services; $132,000 from Medicare under the initial method of reimbursement for supervisory services; and $186,000 from the facility in profit sharing dividends.

A physician employee of another facility received during a 1-year period: $56,000 for administrative services; $121,900 from the Medicare carrier for supervisory services; free hospitalization and professional liability insurance; the use of 1,000 square feet of space at $10 a month for his private medical practice; and about $25,000 from Medicare for non-ESRD related services.

The nation's largest ESRD chain organization paid more than $5.3 million in 1978 to some of the physicians or groups of physicians who operated its facilities. The payments were made for administration of the facility and/or under profit sharing agreements and were generally based on the facilities' profits. The payments were made by the home office and charged back to the facilities through the allocations of home office expenses. The average payment was about $69,000 and ranged from less than $100 to $360,000.

The intermediary auditors did not determine the reasonableness of these payments. The payments were included as part of the facilities' total operating costs which were used to establish the proposed new reimbursement rates. Ten of the 38 independent facilities audited were part of this chain.

MEDICARE HOME DIALYSIS COSTS

HCFA estimated the nationwide median home dialysis per treatment costs for hemodialysis to be $87; $114 for CAPD; and $111 for IPD. We estimated that for the 13 States covered by our review the weighted mean home dialysis per treatment costs to be $103, $110, and $134, respectively. The methodologies used by HCFA and GAO to estimate home dialysis costs differ significantly and would be expected to result in somewhat different cost estimates.

HCFA reviewed home costs for 2,232 patients who obtained their supplies and equipment primarily through 1 of 23 selected facilities for 2 State kidney programs. We reviewed home costs for 656 patients randomly selected from the universe of patients in 13 States regardless of their source of supplies and equipment. The majority (70 percent) of our sample patients obtained their supplies and equipment on their own. Theoretically, we would expect that patients obtaining supplies through a facility, as HCFA's sample patients did, should obtain them at a lower cost because of the advantages of volume purchasing by facilities and hospitals. This could help explain part of the differences between the HCFA and GAO estimates. Because HCFA proposes to use a composite rate covering both home and in facility patients, it probably is more appropriate to use a sample like HCFA's because under the proposed rates most home patients are expected to obtain their supplies through the facility.

HCFA made certain assumptions in developing its estimate of home dialysis costs at the 25 selected locations. While we did not have an opportunity to review all the assumptions HCFA made, we did look at those for the Maryland Kidney Disease Program because the supply costs HCFA found were only about half of what we found. Of HCFA's sample, 107 patients were from the Maryland Kidney Disease Program. To determine the number of home patients in the Maryland program and the number of home treatments they received, HCFA apparently assume that: the number of home patients in the program at year-end represented the average number of home patients for the year; home patients had dialyzed at home all year without any in facility treatments during the year; and home patients obtained all their supplies and equipment through the Maryland program.

The data we obtained from the Maryland program for 1980 show that this was generally not the case. Several of the Maryland program home patients were not getting all their supplies and equiment through the program. Some were getting only drugs and water treatment services. Others were getting only part of their supplies and/or equipment from the program. Our data indicate also that some of the patients were hospitalized or otherwise received in facility treatments during the year. By assuming that the patients got all their services from the program, HCFA's total cost data for patients using the Maryland home program would be understated and by not adjusting for actual time on dialysis or for in facility treatments, the number of treatments used to compute average per treatment costs would be overstated. Both of these would result in an understated average cost per treatment.

As HCFA pointed out in the notice of proposed rulemaking, it is not sure that only reasonable and allowable costs were included in its estimate. Although our estimate includes only costs determined allowable by the Medicare contractors, except for the 122 patients obtaining supplies through hospitals where retroactive adjustments could be made, we are not 100 percent sure that we captured all costs.

We would like to make several observations related to the data we obtained. First, we noted wide ranges in the cost per treatment among patients and among the eight ESRD networks covered by our review. Among the networks average cost per treatment ranged from a low of $81 to a high of $124 for hemodialysis, from $96 to $126 for CAPD, and from $92 to $186 for IPD. Among inidividual patients the ranges were even greater—from $55 to $693 per treatment for hemodialysis, from $46 to $639 for CAPD, and from $56 to $328 for IPD.

A number of factors contribute to the wide ranges including:

The length of time a patient has been on home dialysis. Patients just beginning generally incur substantial start up costs and, thus, new patients have higher average costs. Conversely, patients who have been dialyzing at home for a long period may have purchased their equipment in previous years and would show no equipment costs;

Whether patients need special or additional supplies or equipment such as water treatment equipment in areas with hard water or because of complicating medical conditions;

Whether equipment is owned by the patient or is rented; and

The source used for obtaining supplies and equipment.

HOME DIALYSIS COSTS COULD PROBABLY BE SUBSTANTIALLY LOWERED

Although our cost data for home dialysis treatments is reflective of what Medicare was paying for such services in 1980, we do not believe that it is necessarily representative of the costs that an efficient and economical provider would incur to deliver such services. As discussed below, our data indicate that significant opportunities exist for lowering home dialysis costs.

COMPARISON OF EQUIPMENT RENTAL AND PURCHASE COSTS

About 70 percent of our hemodialysis and IPD sample patients obtained dialysis rental machines from suppliers or the patients' supporting facility. To determine if savings could be realized by purchasing these machines we compared data from four major equipment manufacturers on purchasing, maintaining, and renting their equipment. The data provided covered eight different machines used by home patients. The prices quoted ranged from $6,650 to about $10,030 per machine. Monthly rental charges which generally included maintenance ranged from $370 to about $525. Maintenance contracts ranged in price from $645 per year to about $1,100.

Using this data we computed the difference between purchase and rental costs for a 5-year period, the estimated useful life for the machines. Our computations for these 8 machines showed that the average costs of purchasing would be about $15,800, or about $3,200 a year less than renting it. This equates to a difference of about $20 a treatment. Savings ranged from $11,800 to $21,900.

We visited three VA hospitals to get information on their methods of providing dialysis equipment to home patients. The three hospital purchased the dialysis machines used by their home patients as a cost saving measure. An official at one hospital advised us that this method enabled VA to reissue available equipment to new patients or to transfer it to or from in facility use as the needs demanded. The official said that by owning and properly maintaining their equipment it had lasted well beyond the useful life stated by the manufacturers. He advised us also that there was little administrative burden associated with the management of the equipment once it entered their inventory.

REASONABLE CHARGE AND REASONABLE COST DETERMINATIONS

Suppliers that provide dialysis equipment and supplies for ESRD home patients are generally reimbursed by Medicare carriers on the basis of the reasonable charge for such services. Providers that choose to provide such services for their home patients are usually reimbursed through an intermediary on the basis of reasonable costs. For those home patients for whom we had both the billed and allowed amounts for dialysis equipment and supplies we determined the reduction made to the amounts billed. The data showed a total of about $6 million billed for supplies and about $1.3 million for equipment. These amounts were reduced by the carriers and intermediaries to about $5.8 million for supplies and $1.2 million for equipment for an average reduction of about 3 percent for supplies and 10 percent for equipment. Data published by HCFA on reasonable charge reductions shows that the average reasonable charge reduction for calendar year 1980 for all part B claims was about 22 percent.

Although our costs reflect virtually no reasonable charge reductions for supply charges, we noted large differences in the amounts charged per treatment by different suppliers. For example, for hemodialysis patients, average supply costs ranged from a low of $72 for one supplier to a high of $114 for another. Similar ranges were from $99 to $163 for CAPD and from $67 to $180 for IPD.

About 120 of our sample home patients were getting their supplies through hospitals. Hospital costs are subject to retroactive adjustments based on annual audits. Our computation of the reasonable cost reductions for the hospitals servicing these patients could be over or understated to the extent that retroactive adjustments are made.

VARIATION IN MACHINE RENTAL

As previously stated, about 70 percent of our hemodialysis and IPD sample patients used dialysis machines rented from their support facility or directly from a supplier. The data anlayzed to date show monthly allowed amounts for machines used by hemodialysis patients ranged from $34 to $648. Those allowed for machines used by IPD patients ranged from $125 to $440 per month. The range of machine rental charges allowed for the major sources used were as follows:

Source of machines	*Range of monthly rentals allowed*
Hemodialysis patients:	
Independent facilities	$100 to $615.
Hospitals	$34 to $439.
Cobe	$205 to $364.
Extracorporeal	$192 to $388.
Cascade-Drake	$165 to $409.
Cordis Dow	$330.
Baxter Travenol	$156 to $400.
Organon Teknika	$181 to $439.
Dialysis Inc	$400 to $648.
IPD patients:	
American Medical Products	[1]$125 and $160.
Hospital	$200.
Erika	[1]$125 and $160.
Cascade-Drake	$322 to $346.
Physio Control	[1]$407 and $440.

[1] The higher allowed amounts resulted primarily from a price increase made during the year.

The data available in most instances did not contain information on the rental agreements between the equipment suppliers and the ESRD facilities or patients or specific information on the types and capabilities of rental machines. Therefore, we could not determine to what extent cost differences could be due to the different prices [illegible] for similar machines. Several other factors could account for some or all of the differences. For example, rental rates would vary depending on: whether or not the monthly charges cover maintenance and repairs; whether or not the different machines have the same capabilities; the types of optional or auxiliary equipment included in the agreement; and whether or not provider facilities add a surcharge to the suppliers' equipment charge and the amount of the surcharge.

Surcharges

Several of the independent facilities and hospitals providing equipment and/or supplies for their home patients added a surcharge for their services to the costs at which they obtained the items. The data analyzed to date show that 8 of 12 providers were marking up equipment and/or supply bills by amounts from 10 to 45 percent of their costs. One facility added a flat $25 charge per supply order. Another facility added the lower of $55 or 55 percent to each order, usually $55. Other facilities which provided this service did not charge for it.

Two of the hospitals that added a surcharge for supplies received the bulk supplies and redistributed them to their home patients. Three others merely ordered the supplies and processed the claims. The supplies were shipped directly to the home patients. We do not have enough information to determine the arrangements used by the remaining providers.

ESRD NETWORKS

The 1978 Amendments provided for the establishment of renal disease network organizations as a means of assuring effective and efficient administration of ESRD Medicare benefits. A total of 32 network organizations were established to cover all geographic areas of the country. Membership in these organizations is generally made up of representatives from each of the ESRD facilities within the networks area and consumer representatives. Responsibilities given to the networks included: encouraging the use of the most effective treatment settings; developing criteria and standards for quality and appropriate patient care; setting network goals for placing patients in self-care settings and for kidney transplants; working with facilities to meet network goals; evaluating procedures used by facilities and providers to assess the appropriateness of patients for treatment modes; and submitting periodic reports to HHS on goals, performance, and projected service needs.

We made a limited evaluation of the effectiveness of the networks in carrying out these responsibilities. Our evaluation covered 8 of the 32 networks and consisted primarily of: reviewing the organizational structure of the networks, annual reports, network policies and procedures relating to goals and objectives, and the criteria and procedures used for their certification of need reviews; discussing network responsibilities and performance with network officials; and obtaining the views of selected facility officials on the effectiveness of the networks.

Our review indicates that most of the networks covered by our review had not met all the requirements of the 1978 amendments. Some appeared to be operating more as data gatherers and reporters than as acitive participants in the planning and directing of renal disease services within their respective areas. In this respect, the networks were able to provide us much home patient data. The data provided in most instances was not readily available from HCFA.

The organizational structures of the networks reviewed generally conformed with statutory requirements. All had established goals to increase the number of home patients and kidney transplants. Although these goals were met in many instances, many of the goals reviewed were more in the nature of projections based on prior years experiences than attainable objectives the facilities should strive to achieve to increase the use of these two methods of treatments. At the time of our review, most of the eight networks had not developed criteria or standards for quality and appropriateness of care. About half had made efforts to evaluate the patient care provided by the facilities in their area.

All the networks had some procedures for reviewing and evaluating applications for the establishment of new facilities or the expansion of existing ones. The procedures and criteria followed and the extent of coordination with other health organizations varied from network to network. The dispositions made of the applications processed during the period of our review would indicate that the networks' recommendations probably did not have much impact on the final decisions made by HCFA because about 50 percent of the applications disapproved by the networks were approved by HCFA.

We visited 18 facilities in 4 of the 8 networks to obtain the views of facility officials on the effectiveness and usefulness of their networks. The officials from eight facilities in two of the networks were of the opinion that the networks were performing useful functions. However, officials at two of these facilities stated they could get by without the networks. Officials from one of the two other facilities visited in these two networks were of the opinion that the networks should not have been established initially because of the conflict of interests involved. Officials at the second facility had no opinions to give since they had had few contacts with the network. The views of the officials from the eight facilities visited in the other two networks were all negative. Officials at six of these facilities thought the networks should be discontinued.

In conclusion, based on the limited work we performed, the networks reviewed did not appear to be very effective in carrying out the objectives of the 1978 amendments. Our conclusion is similar to the views expressed by HCFA officals ~~in~~ September 1981 testimony given before the Health Subcommittee of the Senate Finance Committee. At that time, it was stated that HCFA had little evidence that the networks had successfully accomplished any of their major functions. In addition, it was stated that a few of the networks had had any impact on the quality of care provided. It was stated also that HCFA was not satisfied with the networks' planning activities and that HCFA proposed to eliminate the networks.

ATTACHMENT I.—COSTS AND NUMBER OF TREATMENTS AS REPORTED BY THE FACILITIES AND AS ADJUSTED AS OF SEPTEMBER 1981 BY THE FISCAL INTERMEDIARY, HCFA, AND GAO FOR THE 13 INDEPENDENT FACILITIES

Facility	Costs	Number of treatments	Average costs per treatment	Per treatment adjustment to reported costs (decrease (increase)) [1]
Kidneycare of Florida, Clearwater Unit, Clearwater, Fla.:				
Reported	$516,058	4,248	$121.48	
Intermediary	453,793	4,247	106.85	$14.63
HCFA	453,793	4,247	106.85	0
GAO	430,603	4,247	101.39	5.46
Kidneycare of Florida, Lakeland Unit, Lakeland, Fla.:				
Reported	711,662	5,858	121.49	
Intermediary	565,764	5,671	99.76	21.73
HCFA	565,764	5,671	99.76	0
GAO	551,924	5,671	97.32	2.44
Sarasota Artificial Kidney Center, Sarasota, Fla.:				
Reported	899,502	7,005	128.41	
Intermediary	821,649	7,005	117.29	11.12
HCFA	806,085	7,005	115.07	2.22
GAO	773,006	7,005	110.35	4.72
St. Petersburg Artificial Kidney Center, St. Petersburg, Fla.:				
Reported	1,155,984	9,499	121.70	
Intermediary	1,082,859	9,499	114.00	7.70
HCFA	1,057,984	9,499	111.38	2.62
GAO	1,018,603	9,499	107.23	4.15
Community Dialysis Services of Northwest Georgia, Rome, Ga.:				
Reported	574,158	4,972	115.48	
Intermediary	538,867	4,866	110.74	4.74
HCFA	538,867	4,866	110.74	0
GAO	499,210	4,866	102.59	8.15
Community Dialysis Services of Southwest Georgia, Valdosta, Ga.:				
Reported	710,837	6,699	106.11	
Intermediary	687,013	6,422	106.98	(.87)
HCFA	687,013	6,422	106.98	0
GAO	619,570	6,422	96.48	10.50
Anderson Dialysis Clinic, Inc., Anderson, S.C.:				
Reported	662,858	4,341	152.70	
Intermediary	508,683	4,145	122.72	29.98
HCFA	458,943	4,145	110.72	12.00
GAO	435,724	4,145	105.12	5.60
Florence Dialysis Center, Inc., Florence, S.C.:				
Reported	1,096,007	11,189	97.95	
Intermediary	939,909	10,623	88.48	9.47
HCFA	892,464	10,623	84.01	4.47
GAO	843,240	10,623	79.38	4.63
Florida Parish Artificial Kidney Center, Hammond, La.:				
Reported	683,690	4,271	160.08	
Intermediary	588,915	4,271	137.89	22.19
HCFA	528,607	4,271	123.77	14.12
GAO	483,532	4,271	113.21	10.56
Cape Cod Artificial Kidney Center, Yarmouth, Mass.:				
Reported	516,752	4,513	114.50	
Intermediary	505,214	4,513	111.95	2.55
HCFA	505,214	4,513	111.95	0
GAO	472,847	4,513	104.77	7.18
Dialysis Services of New Hampshire, Inc., Concord, N.H.:				
Reported	1,088,134	7,075	153.80	
Intermediary	980,941	7,188	136.47	17.33
HCFA	866,152	7,188	120.50	15.97
GAO	854,261	7,188	118.85	1.65

ATTACHMENT I.—COSTS AND NUMBER OF TREATMENTS AS REPORTED BY THE FACILITIES AND AS ADJUSTED AS OF SEPTEMBER 1981 BY THE FISCAL INTERMEDIARY, HCFA, AND GAO FOR THE 13 INDEPENDENT FACILITIES—Continued

Facility	Costs	Number of treatments	Average costs per treatment	Per treatment adjustment to reported costs (decrease (increase)) [1]
Southern Connecticut Out of Hospital Dialysis Unit, Inc., Bridgeport, Conn.:				
Reported	1,576,609	11,006	143.25	
Intermediary	1,492,696	10,966	136.12	7.13
HCFA	1,232,666	10,966	112.41	23.71
GAO	1,230,693	10,966	112.23	.18
The Kidney Center, Boston, Mass.:				
Reported	5,165,798	46,886	110.18	
Intermediary	4,786,213	46,515	102.90	7.28
HCFA.	4,768,381	46,515	102.51	.39
GAO	4,456,291	46,515	95.80	6.71

[1] Represents the extent of adjustments beyond those made by the immediately preceding organizations.

ATTACHMENT II.—TOTAL COST REPORTED AND GAO'S ESTIMATE OF TRANSACTIONS WITH RELATED ORGANIZATIONS FOR THE 13 INDEPENDENT FACILITIES

Facility	Total reported costs	Related organization transactions	
		GAO estimated costs	Percentage of total reported costs
Kidneycare of Florida, Clearwater Unit, Clearwater, Fla	$516,058	$286,825	56
Kidneycare of Florida, Lakeland Unit, Lakeland, Fla	711,662	352,471	50
Sarasota Artificial Kidney Center, Sarasota, Fla	999,502	415,551	46
St. Petersburg Artificial Kidney Center, St. Petersburg, Fla	1,155,984	540,624	47
Community Dialysis Services of Northwest Georgia, Rome, Ga	574,158	155,619	27
Community Dialysis Services of Southwest Georgia, Valdosta, Ga	710,837	212,503	30
Anderson Dialysis Clinic, Inc., Anderson, S.C	662,858	291,891	44
Florence Dialysis Center, Inc., Florence, S.C	1,096,007	514,083	47
Florida Parish Artificial Kidney Center, Hammond, La	583,690	302,166	44
Cape Cod Artificial Kidney Center, Yarmouth, Mass	516,752	225,956	44
Dialysis Services of New Hampshire, Inc., Concord, N.H	1,088,134	105,110	10
Southern Connecticut Out of Hospital Dialysis Unit, Bridgeport, Conn	1,576,609	0	0
The Kidney Center, Boston, Mass	5,165,798	2,577,169	50

STATEMENT OF THE AMERICAN ASSOCIATION OF NEPHROLOGY NURSES AND TECHNICIANS

The American Association of Nephrology Nurses and Technicians is a 3,500 member group of care givers who provide direct care to end-stage renal disease (ESRD) patients.

The issues we address relate to our concerns about changes in the reimbursement regulations (February 12, 1982 NPRM) governing the ESRD program.

1. LABOR WAGE INDEX AND CERTIFICATION

We are pleased that some of the issues raised previously are being restudied in regard to the impact on care of the ESRD patient. We understand that HCFA is looking very closely at the concept of the Bureau of Labor Statistics Labor Wage Index as a component of the proposed composite rate reimbursement system. We sincerely hope that there will be some revision so that patients will not be denied access to treatment and that patient-staff ratios will not be compromised.

Secondly, we note that HCFA does intend to continue the certification process. We note, however, that no time span between surveys is mentioned AANNT continues to support a survey process—a more meaningful one than was previously in existence. We have stated in prior statements that the survey team should include nephrology professionals to perform a peer-review function.

2. TREATMENT OPTIONS

AANNT continues to support the concept that all patients should have all treatment options presented to them. It is unfortunate that HCFA must (as stated in Dr. Davis' testimony of April 22, 1982) continue to discuss offering incentives to the physician in order to increase the number of patients referred for home dialysis. It seems that every patient should be informed of all the options and be the prime decision-maker in the majority of cases.

We certainly agree that a larger proportion of patients could be referred both to home dialysis (either hemodialysis or peritoneal dialysis) or transplantation than is currently reflected in the national percentages.

3. HOME DIALYSIS TRAINING AND REGIONALIZATION

Home dialysis training (both hemodialysis and peritoneal dialysis) is performed daily throughout the U.S. by nurse and technician staff. It is imperative the qualified professional nurses be hired to phase-in the training programs. This involves planning program objectives, sequencing topics, designing teaching/learning strategies, and developing evaluation criteria and tools. A minimum of six months planning is required to accomplish adequate preparation for a well-executed home training program.

It might be wise for groups of facilities to establish regional home training programs. A mechanism would have to be devised to: a. Reimburse the training unit appropriately, or b. Assure proper incentive reimbursement to the referring facility and the facility providing the support and monitoring of the patient (whether they are the same or different).

4. HCFA MANUAL FOR SELF-DIALYSIS

HCFA published (through the Government Printing Office) a Self-Dialysis Manual which was completed in April 1981, under the auspices of System Sciences, Inc. HCFA's intention was to disseminate one copy of the manual to every ESRD unit in the country via the 32 Network Directors. Unfortunately, through verbal feedback at AANNT's Annual Symposium (April 13–15, 1982) many head nurses came forward stating they had not yet received their copy. If HCFA intends to encourage self-dialysis (both at home and in-center), then this manual should be widely disseminated as a basic resource.

5. RESEARCH STUDIES

AANNT supports further research as is being suggested by the ESRD Rehabilitation Task Force under the direction of Dr. Robert Gutman. This task force has volunteers from several of the nephrology provider groups, and several other Federal agencies besides the HCFA ESRD program staff. We also support continued funding to the Orkand Corporation to complete its evaluation of the Home Dialysis Paid-Aide Study.

Finally, the results of a very significant Patient Acuity Study is now available through ESRD Network No. 3 (San Francisco). Their preliminary data suggests that there are differences in acuity between hospital-based dialysis patients and free-standing facility dialysis patients. Their report will be available in approximately four weeks.

6. PATIENT CASE-MIX IN "CENTERS" AND "FACILITIES"

We are all aware that the case-mix issue is complex. In reviewing the definition of a "facility" and a "center", we note that a hospital-based dialysis "facility" (as defined in the 1976 rules and regulations) must have at least an 80 percent chronic patient population. Acuity is not the major issue here. The case-mix in this instance tends to be the same as that at an independent free-standing dialysis facility. There are many reasons why a chronic dialysis service may be based in a hospital structure.

If, on the other hand, a hospital-based unit is defined as a "center", then it can serve no more than a 20 percent chronic patient population. Theoretically, these chronic patients are more unstable, requiring dialysis with close supervision, and the availability of all hospital resources. If, however, the "center" is the only available dialysis service in that geographic area, then those patients may not be unstable as previously described. We are aware that many hospital-based units, for which HCFA intends to reimburse at a higher rate, are in the former category as a "facility".

AANNT will gladly assist in any research projects which attempt to clarify and define the acuity levels of patients at all types of dialysis units. This is an extremely important issue that all provider groups should assist HCFA to define for ourselves and for Congress.

7. PHASE-IN PERIOD

We are pleased that HCFA is considering a phase-in period so that the program can proceed in an orderly fashion. Historically, rapid change in reimbursement methodology has resulted in inefficient cost recovery resulting in financial hardships to facilities.

CONCLUSION

Nephrology nursing and technology is an extremely challenging field of endeavor. We have hundreds of expert nephrology nurse clinicians who function as staff nurses, head nurses, nurse-practitioners and clinical specialists. They are experienced in providing comprehensive nursing care daily to a physiologically and psychologically very complex group of patients. Nephrology nurses have proven themselves quite competent in providing care to this chronic patient population.

At the heart of the enterprise of caring, AANNT recommends that we all attempt to strike a balance between an adequate structure for service and an orderly process of primary care. Caring is a very serious business. We need to be concerned about individual human dignity so that one idea or one program is not advanced at the expense of another. AANNT will do all that it can to assist in accomplishing that goal.

Statement of the American Medical Association

The American Medical Association takes this opportunity to submit this statement in response to the Subcommittee' request for comments on the Health Care Financing Administration's proposed rule to alter the reimbursement nechanisms by which Medicare pays for dialysis facility and related physician services. The proposed regulation would establish a prospective reimbursement rate for dialysis services and radically alter the End-Stage Renal Disease (ESRD) program that was enacted by Congress in 1972.

When the ESRD program began in 1974, it served a patient population of 11,000 at a cost of approximately $228 million. In the ensuing years, the ESRD program has witnessed significant growth. According to a March 1982 document prepared by the Senate Finance Committee staff for the use of the Committee (CP 97-12), the ESRD program was benefitting a dialysis population of 47,369 patients in 1980. Approximately half of these patients were treated in hospital-based facilities and the other half in independent facilities. The 1979 cost of the ESRD program was $850.5 million, with the projected 1982 cost set by the Health Care Financing Administration (HCFA) at $1.8 billion. (Other figures set the 1981 ESRD patient population at 68,200 patient, with a program expense of $1.5 billion.) The proposed rule would dramatically alter this extensive program by substituting an untried prospective reimbursement methodology for the existing per treatment reimbursement system.

The AMA opposes the implementation of this proposed rule. The AMA is concerned that the proposed rule could have the effect of limiting access to ERSD treatment facilities and services. Such an inappropriate result was certainly not the intent of Congress in 1972 when the ESRD program was formed, nor was it the intent of Congress in 1978 or 1981 when the Social Security Act was amended to authorize prospective reimbursement for ESRD services. Minimally, such major changes should be attempted on a limited scale prior to their being imposed upon the over 65,000 patients whose very lives are dependent upon the ESRD program.

BACKGROUND

The ESRD program was enacted by Congress in 1972 to provided Medicare coverage for ESRD patients meeting certain entitlement requirements. This program was developed because few individuals could afford the cost of necessary treatment to stay alive, and few institutions provided this treatment. In passing the Social Security Amendments of 1972, Public Law 92-603, Congress extended the Medicare program to pay for the cost of ESRD treatment for almost all individuals suffering from ESRD. This basic legislation was modified in 1978 to encourage the use of lower cost treatment modalities, and prospective reimbursment for ESRD treatment was authorized. HCFA issued a proposed rule in September 1980 that would have established a single prospective reimbursement rate for renal dialysis services provided in hospitals and free-standing facilities. Before this proposed rule could be implemented, Congress again amended this section of the Social Security Act. This 1981 amendment called for the creation of prospective reimbursement formulas that would take into account both ESRD services furnished in a hospital-based facility and services furnished in other renal dialysis facilities, or "based on such other method or combination of methods which differentiate between hospital-based facilities and other renal dialysis facilities."

The proposed rule would establish two prospective reimbursement rates for dialysis services based on the facility where the services are furnished. Services furnished in an independent facility would be reimbursed on a prospective basis at $128, and servives furnished in a hospital-based facility would be reimbursed on a prospective basis at $132. These rates are purported to be based on the combined median rate for the delivery of dialysis services in both hospital-based and independent facilities, and the slightly higher rate to the hospital is intended to reflect the higher costs of delivering these services in hospitals.

The proposed rule would also eliminate the fee-for-service methodology of payment of physician fees for furnishing dialysis services. Physicians would receive the same monthly capitation payment for both home and in-facility dialysis, based upon a weighted formula that accounts for the proportion of patients currently dialyzing at home. Under the proposed rule, the average monthly capitation payment for physicians' services would be $184.08. This figure would not be automatically updated by the carrier's prevailing charge data. However, HCFA will retain the right to review physician reimbursement and change the reimbursement rate accordingly.

COMMENTS

The American Medical Association is very concerned that the proposed regulation could have the unanticipated effect of restricting access to care for the very individuals for whom the ESRD program was designed. By basing the reimbursement amount for ESRD services at the median costs for all facilities, it is readily apparent that a significant number of independent facilities and hospital-based facilities survival, even with the minor adjustment for hospital-based facilities. This result was clearly shown in an analysis done for the Senate Finance Committee (CP 97-12) on the net effect of the proposed rates on the sample facilities surveyed by HCFA for the creation of the rates. According to this analysis, 50 hospital-based facilities would suffer losses while only 14 would experience a profit; and 9 independent facilities would experience losses whole 29 would experience a profit.

Our concern that this proposed rule would cause ESRD facilities to shut their doors is real. While the proposal does include incentives through higher reimbursement for home dialysis, these incentives will most likely prove to be inadequate to maintain facilities where the patients are either unable or unwilling to dialysis at home. The situation is further complicated by the fact that final regualtions, if issued, would be effective on the date of their publication. This lack of any transition period would force many facilities that already operate on a "reasonable cost" basis to face immediate economic crisis.

We also recognize that the proposed rule does provide for additional reimbursement to facilities that receive an "exception request." It is reasonable to anticipate that a significant number of ESRD facilities will apply for exceptions. Under the existing reimbursement structure, approximately 300 of the 975 ESRD facilities in existence in 1979 did request authorization for a payment rate above the national payment limit. Even with reimbursement set at a significantly higher rate under the existing structure in comparison to the proposed rule, 278 exception requests were approved in full or in part in 1979. The proposed rule would only exacerbate a situation where almost one third of the existing ESRD facilities find the current $138 national payment limit inadequate.

The concerns that we have expressed are buttressed by recent testimony by the National Association of Patients on Hemodialysis and Transplantation, Inc. given before the Senate Finance Committee on March 15, 1982. That Association stated that:

"The current proposal has created a great deal of anxiety in the patient community. As an Association, we are deeply concerned that the result of these proposals will be to decrease the quality of care currently available to patients and to cause the re-establishment of selection criteria for the treatment of kidney failure, resulting in constriction of service to those who require it. In more simple terms, this implies the real possibility that persons whose lives could be saved willl not be treated and will therefore die. We view such a possibility with the greatest alarm and see it as contrary to P.L. 92-603, which guaranteed reimbursement for dialysis and transplant therapy for all those eligible through the Social Security Act. * * * We ask this Committee and this Administration one question: What will happen to the patients now being treated in the facilities which currently have costs higher than the reimbursement they will receive if these new rates are enacted? According to HCFA's own analysis, 'these rates would result in reimbursing 46 percent of all hospital-based facilities and 28 percent of all independent facilities at a rate per treatment below their current costs for in-facility dialysis.' "

By establishing the authority for prospective reimbursement in 1978, Congress was looking for mechanisms to reduce the increase in the costs of the ESRD program. However, Congress did not anticipate that prospective reimbursement could be imposed over the extensive ESRD program with one single all-inclusive action. Indeed, the Senate Finance Committee anticipated testing and a gradual phasing-in of these incentives. In first providing for prospectively set rates for ESRD services, the Senate Finance Committee stated that "although the bill authorizes the use of various types of incentives for more efficient delivery of services, it is recognized that some testing and phasing-in of these incentives may be necessary" (Senate Finance Committee Report on H.R. 8423, No. 95-714).

The AMA believes that implementation of the proposed rule on a nationwide scale would place some ESRD patients in jeopardy for their lives, and this risk is unacceptable.

The American Medical Association also believes that the proposed rule should be withdrawn because of problems inherent with the methodology for establishing reimbursement rates. We must first question the propriety of the essentially single reimbursement rate, since a dual rate was called for in the 1981 amendment to the Social Security Act. The Senate Finance Committee staff report states that "the proposal to base a dual rate on the median costs of all facilities and then adjusting that median to some extent for hospital-based facilities does not address the concerns of the committee." The arbitrary nature of the reimbursement level is also emphasized by the fact that the median of ESRD facility costs is used in setting the prospective rate, with 46 percent of hospital-based facilities and 28 percent of independent facilities actually being reimbursed below their current costs.

CONCLUSION

The proposed regulation creates the significant potential that some ESRD patients will not have access to needed facilities, and the proposed methodology and calculations in setting the prospective rates is inappropriate and arbitrary. The very fact that the proposal would result in half of the dialysis facilities being reimbursed at a level below their actual costs indicates that the proposed level of reimbursement is inequitable.

The American Medical Association strongly believes that any new reimbursement scheme should be tested and evaluated on a limited basis prior to nationwide implementaton. Through actual experience it would be possible to identify problems and prevent those same problems from developing on a broader scale.

In light of our comments, the AMA urges the Committee to work for the withdrawal of the proposed rule. We believe that appropriate representatives from both the public and private sector should meet to discuss and develop equitable methodologies for prospective reimbursement of dialysis services that would first be tried on a limited scale to ascertain their viability.

THE UNIVERSITY OF ARIZONA HEALTH SCIENCES CENTER,
DEPARTMENT OF INTERNAL MEDICINE, SECTION OF RENAL DISEASE,
Tucson, Ariz., April 26, 1982.

JOHN J. SALMON,
Chief Counsel, Committee on Ways and Means, Subcommittee on Oversight, Longworth House Office Building, Washington, D.C.

DEAR MR. SALMON. The first comprehensive national data concerning the ESRD Program became available just a few days ago, and reveals surprising trends in the

ESRD Program that impact significantly on several aspects of the sweeping changes in the Program proposed in the NPR published Feb. 12, 1982.

This data, submitted on HCFA form 2744 by each ESRD facility has, for the past 2 years, been summarized by each of the 32 ESRD Networks, and forwarded to the HCFA. One of the Networks recently collated and computer analyzed the data from all 32 Networks through Dec. 31, 1981. The latest data includes an analysis of 59078 patients. This data is the most complete, the most recent, and by far the most interesting we have ever had concerning this one billion dollar plus program. Apparently the HCFA has not yet analyzed this data, or they would have known that much of what the new proposed regulations intend to encourage, has, in fact, already occurred—not by regulation, but by recognition by the members of the dialysis community of significant technologic advances and application of these advances to ESRD care.

The proposed regulations make repeated reference to inadequate or incomplete data; use small, sometimes hasty and obviously biased audits to draw important conclusions; and recommend substantial changes in a model program that has successfully met a rapidly increasing need, and done so at a modest increase of only 20 percent in cost per service rendered in 8 years, at the same time the medical portion of the CLI has increased 96 percent.

The new data reveals that from Jan. 1, 1980 through June 30, 1980, 5066 new patients entered the ESRD Program. During the same time period, 2032 patients completed a course of self dialysis, training for home hemodialysis, home peritoneal dialysis, or continuous ambulatory peritoneal dialysis (CAPD). Thus, the proportion of patients completing home training to those entering dialysis for the first time was 40 percent! During the period from July 1, 1980 through Dec. 31, 1980, 2416 patients completed home training and 4802 entered dialysis for the first time—a proportion of 50 percent! During the period Jan. 1, 1981 through June 30, 1981, 5479 patients entered dialysis, and 2688 or 49 percent completed home training. Finally, during the most recent 6 month period, July 1, 1981 through Dec. 31, 1981, 5288 patients began dialysis and 2591, or 49 percent, completed home training.

Since this very current data reveals that the more than 1000 facilities that provide ESRD care are already training approximately half of new program entrants for home dialysis, the very premise on which the new proposed regulations is based—that is, achieving economy of operation by encouraging home dialysis, and permitting continued operation of center dialysis (which the regulations indicate would operate at a slight loss) by encouraging home dialysis—is patently fallacious. The economies expected have already been utilized by facilities to continue to operate successfully in the inflationary economy of the past several years without a significant increase in per procedure reimbursement.

Implementation of the proposed regulations, in view of the changes that have not been previously recognized but have already occurred, could be absolutely catastrophic to the present, highly successful, ESRD care system. It would be unconscionable to proceed to implement regulations based on inaccurate and outmoded assumptions now that these striking changes in care patterns are known. It is imperative that no new regulations be confirmed until a complete reexamination can be conducted, and meaningful exchange of thinking is achieved between appropriate personnel in the HCFA and knowledgeable members of all elements of the dialysis and transplant communities.

Sincerely,

DAVID A. OGDEN, M.D.,
Chief, Renal Section and Professor of Medicine.

ASSOCIATION OF AMERICAN MEDICAL COLLEGES,
Washington, D.C., April 22, 1982.

Hon. ANDREW JACOBS, Jr.,
Chairman, Subcommittee on Health, Committee on Ways and Means, House of Representatives, Longworth House Office Building, Washington, D.C.

DEAR MR. JACOBS: The Association of American Medical colleges is submitting for inclusion in the April 22nd hearing record its comments on the Administration's proposed regulations governing reimbursement under the Medicare End-Stage Renal Dialysis Program. As the organization representing the teaching hospitals of the United States, the AAMC is concerned about the impact of the proposed regulations on teaching hospitals that provide hospital-based outpatient dialysis.

However, it is not merely the negative financial impact of the rates established by these regulations to which exception is taken. The discrepancy between the ostensible purpose of the regulations and their proposed implementation and the manner in which the rates have been formulated are also matters of concern. As will be further discussed, the deficiency in the regulations stems both from the methodology and the data base used to establish the proposed rate setting structure. Furthermore, the lack of definitional clarity in the exception process indicates the lack of commitment to use it as a mechanism for adjusting rates.

Prior to expanding on the above points, the motivation for the publication of these regulations should be analyzed. Cost containment and reduction in federal programs is obviously a high priority of this Administration. In furtherance of this goal, the ESRD Program became a subject of scrutiny. The publication issued by the Department of Health and Human Services (DHHS) in the Federal Register of February 13, 1982 proposing the regulations, acknowledged that the ESRD Program has generally been successful in its mission to protect renal disease patients from the catastrophic costs of needed care. The proposed rule then goes on to state:

"The major problem is the high and steadily rising cost of the program and the burden it can place on the Medicare trust funds unless steps are taken to make it more cost-effective."

Review of the history of this program, however, demonstrates that this is simply not the case of a "cost-ineffective" federal program. When the program began operation in 1974, there were 11,000 patients receiving dialysis services under Medicare at a cost of $229 million . . . a yearly cost of $20,800 per patient. In 1981 there were 68,200 patients receiving dialysis under the program at a cost to Medicare of approximately $1.5 billion . . . a yearly cost of $22,000 per patient. In this seven year span, the number of patients enrolled increased by six fold. However, the cost per patient increased only 5.8 percent. Thus, it has been patient demand, not "cost-ineffectiveness" that has resulted in the increase in Medicare funds required for this program.

However, having identified the escalating program costs as being a function of cost-ineffectiveness, the proposed regulations will not have the effect of promoting greater use of home dialysis and thus lowering these costs. While home dialysis is a less expensive mode of treatment and its increased use has been advocated by the Congress, it is undeniably true that there is a subset of patient who because of medical, psychological or logistical reasons are unsuited for home dialysis. In recognition of this, HCFA's goal of increasing home dialysis is to have 30–40 percent of dialysis treatments being done in patients' homes within five to seven years. Currently, 23.5 percent of all hospital-based ESRD patients dialyze at home while only 10.5 percent of independent-based ESRD patients dialyze at home. Yet, the effect of these regulations, as will be more fully set forth below, will be to cause hospital-based facilities to greatly reduce or to consider seriously the future existence of their dialysis programs. If this occurs, that sector of the provider community which is currently responsible for achieving two-thirds of HCFA's goal of 30–40 percent home dialysis within the next five to seven years, would be greatly reduced and the source of the impetus for home dialysis constricted.

THE RATE STRUCTURE ESTABLISHED BY THESE REGULATIONS IS DEFICIENT WITH REGARD TO THE DATA AND METHODOLOGY USED TO ESTABLISH THE RATE STRUCTURE

Under the proposed regulations, Medicare would reimburse hospitals for outpatient dialysis at $132 per treatment and independent facilities at $128 per treatment. An analysis of how these rates were determined reveals the problem with accepting their validity. When an agency sets out to establish a new rate structure and methodology to justify these rates, the burden should be on the agency to demonstrate that the methodology and resulting rates are soundly based on established factual data. One fundamental difficulty with the new rates is that such data was not generated by HCFA.

The data used by HCFA in establishing the rates were up to five years old. The regulations proposed rates for fiscal year 1983; however, these rates were based on cost data for the period 1977 to 1979. While HCFA states that an adjustment factor of 5 percent for hospital-based services has been used to allow for this time lag or for problems with the data, this figure was arbitrarily chosen; it had no rationale behind its use. No provision in establishing the rules was made for the effect of inflation.

In addition to the problems with the age of the data, there is also a problem with respect to the unit of analysis (dialysis treatment) . . . its characteristics and the resources necessary to produce it. HCFA's statement on page 6561 of the Federal Register publication is instructive in this regard:

"However, it is important to recognize that while dialysis treatments are generally comparable from patient to patient and setting to setting, we do not have a uniformly accepted definitive model for a dialysis session. There are no uniform standards for the numbers and qualifications of personnel, or for staff to patient ratios, and the dialysis service seems to vary in intensity of care depending on the patient's health status."

In determining the costs incurred by dialysis facilities, HCFA surveyed 70 of the 537 hospital-based facilities and 40 of the 288 independent facilities. When the DHHS Inspector General reviewed the survey and audit procedure employed by HCFA, he found it to be considerably lacking. He found that the audits were insufficient and result in overstating costs with regard to independents. His conclusion concerning the manner in which the audits were done provides sufficient concern to question the results.

Richard Kusserow, the Inspector General, testified before the House Subcommittee on Intergovernmental Relations and Human Resources of the Committee on Government Operations on February 23, 1982. He addressed the issue of the data collection and certain of his comments are instructive. He noted that the HCFA review of the facilities was a survey type of review rather than a field audit. He went on to say that there had been indecision in formulating a plan to scientifically sample facilities to be audited, and he would like to have seen more comprehensive audits performed. He said he believed that fuller scope audits would have provided more assurance that the data collected would provide a more reasonable basis for starting the setting of these incentive rates.

Dr. James Donovan, the Associate Administrator for Management and Services for HCFA was a speaker at a dinner meeting on the ESRD Program sponsored by the National Health Policy Forum of the George Washington University on March 25, 1982. He candidly admitted that the data base used for the setting of the new rates "left a lot to be desired." This situation of an inadequate system of cost data retrieval has been exacerbated by the fact that none of the facilities was afforded the opportunity to appeal costs excluded during the survey process.

Compounding the deficiencies of an outdated and inadequate collection of cost data was the ultimate methodology used by HCFA to establish the rates. At the outset, it should be noted that Congress in the Omnibus Budget Reconciliation Act of 1981 directed the DHHS to establish ESRD reimbursement rates to provide incentives for efficient and economic delivery of renal dialysis services. Congress further directed the Department to set a dual composite rate for hospital and independent facilities so that the dual rate would reflect the relative costs of providing such services. HCFA recognized the mandate from Congress to differentiate between hospital-based and independent facilities. While the published rates are different for the two types of facilities, the reality is that a single methodology of ascertaining costs was used with a "K" factor applied to differentiate between the entities.

Again, the testimony of the DHHS Inspector General corroborates this point. Mr. Kusserow stated that he did not believe HCFA's rate proposal met the statutory requirement of a dual composite rate. Rather, it was a single rate for independent facilities with a factor built in for hospitals. This criticism was contained in Mr. Kusserow's November 12, 1981 Nonconcurrence Memo regarding HCFA's rate proposal.

Dr. Carolyne Davis, HCFA Administrator, also testified before the House Subcommittee on Intergovernmental Relations and Human Resources of the Committee on Government Operations on February 24, 1982. In the course of her testimony, she acknowledged that in calculating the treatment costs, HCFA combined independent facility cost data with hospital cost data. This comingling of cost data is contrary to the congressional directive to establish a dual rate structure.

An example of the application of this comingling demonstrates the inadequacy of its use. Hospital-based facilities incurred labor costs of $61.17 per treatment, while the independent facilities' labor costs per treatment were found to be $40.79. The higher hospital costs reflect the more intensive labor requirements of dialyzing a sicker population of patients. HCFA incorporated both these figures in generating a labor cost for all facilities. This was in disregard of the need to differentiate between the two typs of facilities and resulted in a rate structure detrimental to the hospital-based facilities. This result was candidly recognized at the Februry 23 hearing by Mr. Larry Simmons, the Acting Associate Director of the Office of the DHHS Inspector General when he stated his view that the proposed rates would on one hand unfairly penalize the hospitals without giving sufficient recognition to the costs that HCFA collected in their audits of the sample of hospitals. At the same time he indicated it would result in undue enrichment to some of the other free-standing facilities.

As noted above, the proposed regulations make an attempt to differentiate between the two types of facilities by setting the rate for hospital-based facilities at 1.05 of the median cost. This factor is to allow for the possibility that HCFA's methodology failed to recognize the legitimate costs of hospitals. However, there is no explanation in the regulations as to how this factor was derived. In fact, it was arbitrarily chosen as demonstrated by the testimony of Dr. Carolyne Davis who said HCFA could have picked any figure but wanted to keep it to a minimum from a cost point of view.

Finally, there is strong reason to believe that the proposed rates were not determined after having applied a methodology which resulted in their generation. Rather, it appears HCFA first established how much it wanted to save from the ESRD Program and then worked backward to establish a rate structure which would yield that result. A November, 1981 Decision Memorandum to the DHHS Secretary from HCFA Administrator Davis presented for consideration two options to use for rate setting. The methodologies were quite different, yet despite the difference in the formulae of these options, the final dollar amounts to be allowed per treatment for both independents and hospital-based facilities were identical. This scenario was brought up by Chairman Fountain during his Subcommittee examination of Mr. Kusserow. Chairman Fountain asked him whether it appeared that HCFA first determined how much it wanted to pay and then decided how to justify the rates. Mr. Kusserow indicated he did not know, but that it was possible. Surely this point is so important it deserves an answer.

Thus, in a setting of rate making where the burden is on the agency to have clear data and a rationale for the rate structure, we are confronted with regulations based on old data which was inadequately retrieved as acknowledged by officials of the DHHS among others. These regulations fail to carry out the Congressional mandate to establish dual rates for hospital-based and independent facilities, but merely give token acknowledgement of that mandate by using an adjustment factor arbitrarily chosen and without rational basis. These deficiencies are further compounded by evidence which would indicate that the rate structure was preordained to yield a certain savings and any methodology used would have given identical rates. Such results obviously must severely call into question the legitimacy of a regulatory process which is ostensibly designed to establish rates based on an objective analysis of the cost data incurred by the facilities being regulated.

HCFA'S FAILURE TO RECOGNIZE THE DIFFERENCE IN PATIENTS TREATED AT HOSPITAL-BASED FACILITIES FROM THOSE TREATED AT INDEPENDENT FACILITIES REPRESENTS A FUNDAMENTAL FLAW IN ITS METHODOLOGY

The population of patients who are dialyzed as outpatients at hospital-based facilities comprise two subsets. One subset consists of those stable chronic renal failure patients who may be dialyzed at a free-standing independent facility as easily as at the hospital. The second subset consists of those patients who because of complications secondary to their renal disease or due to other secondary diagnoses are so potentially unstable that they warrant hospital-based dialysis. It is the need to provide dialysis for this latter subset of patients that results in the disparity of costs between hospital-based and free-standing facilities.

The explanation for the greater costs for such hospital-based facilities derives from their increased labor and overhead costs. The complicated patients require more experienced personnel (registered nurses to provide the dialysis treatments). Freestanding entities can use technicians who are capable of placing a patient on the machine and disconnecting that patient four hours later. However, if that patient demonstrates any signs of instability, he no longer will be dialyzed at such a facility because the personnel are not trained to deal with complications. Such patients subsequently are transferred to a hospital-based facility. Furthermore, hospital-based facilities incur greater costs in the form of monitoring equipment which enables nurses to quickly observe possible problems and adjust the dialysis treatments accordingly.

Other factors influencing the cost differential include the longer time per treatment for patients who are sicker than those dialyzed at free-standing facilities. For instance, patients with cardiovascular disease must dialyze at a slower rate in order to prevent the exacerbation of a common side effect of hemodialysis, hypotension. If these patients become hypotensive they are in danger of suffering arrythmias, chest pain, myocardial infarction or cerebrovascular insufficiency. Consequently, the longer the time necessary to dialyze the patient the higher the cost per treatment.

Another such factor contributing to longer sessions is the practice of hospital-based facilities encouraging the patient to actively participate in the dialyzing process. This includes the patient placing himself on the machine and his further involvement with the procedures used for dialysis. This process has been found to be beneficial with regard to fostering patient compliance and a sense of involvement with therapy. However, by providing this sense of involvement the dialysis process is lower than using an experienced technician to work with the patient as a passive recipient. Admittedly, this participation results in increased costs but these costs are considered a justifiable expense in providing the most efficacious treatment of the patient. Furthermore, and as discussed above, it is the hospital-based facilities which are providing the bulk of home dialysis. Maintaining such programs with this attendant patient education costs is another contributing factor to the increased cost of hospital-based services.

HCFA has been unwilling to acknowledge that this subset of sicker patients being dialyzed at hospital-based facilities exists. On page 6564 of the Federal Register in which the proposed rule is published it is stated that: "Some hospital units claim that one reason they have higher labor costs than independent facilities is that they treat more patients with multiple conditions or other complications (including the elderly and pediatric patients). They require more highly trained staff and more staff per patient. The data presently available to use (sic) through our medical information system do not support this claim. We have examined age, sex, race and utilization rate (discharges and days of care) differences between hospital-based and free-standing facilities. The differences were small and did not approach statistical significance. We conclude, therefore, that with respect to these measures of patient need, there is no great difference between hospital-based and independent facilities." 47 Federal Register, 6564.

The fallacy in such a position is that the factors HCFA used to compare the types of patients (age, sex, race and utilization rate) are not the factors to analyze to make such a determination. That is, within the secondary diagnosis there is a continuum of variable patient condition from that of stable to unstable. Unstable patients should not be dialyzed at free-standing facilities and should be referred to hospitals where more knowledgeable staff and monitoring facilities are present in case these patients develop complications resulting in the necessity for hospitalization.

Recognition of the different patient population served by the hospital-based facilities is evidenced by the fact that independent facilities will send their sicker, more complicated patients to the hospital for dialysis if there is an indication of instability. For example, the Beth Israel Hospital in Boston has an outpatient dialysis facility. Forty percent of the patients treated there were referred from free-standing facilities because they were to unstable to be confidently dialyzed by those facilities. The remainder are patients who have required hospital-based dialysis since their diagnosis. The experience of the Beth Israel Hospital is not unique from that of other teaching hospitals across the country.

Notwithstanding the position of HCFA published in the Federal Register the testimony elicited by the Subcommittee on Intergovernmental Relations and Human Resources reveals that higher hospital-based costs do reflect the care for a sicker population of patients. Mr. Richard Kusserow acknowledged that there was enough data to indicate that the patient mix is different between free-standing and hospital-based facilities. At that hearing there was also reference made to a HCFA memorandum of August 18, 1980 written by Mr. Frank Doyle of the Division of Alternative Reimbursement stating: "The results infer that there is a difference in some of the characteristics of patients in a hospital and nonhospital setting * * * such that it would be reasonable to expect that this difference would cause hospitals to incur additional costs."

Although Dr. Davis' testimony attempted to explain away this memorandum, she herself acknowledged that hospitals may have sicker patients but felt that this would be provided for by the exception process. However, the exception process is inadequate to meet this need. Again, it must be remembered that Congress directed the establishment of a dual rate which was to reflect the difference in hospital-based costs; a difference occasioned by the type of patients treated. The development of the regulations failed to allow for this difference in the rates.

THE EXCEPTION PROCESS IS INADEQUATE TO PROVIDE HOSPITAL-BASED FACILITIES RELIEF FROM THE PROPOSED RATES

Under the current system of cost reimbursement, the base of $138 per treatment is almost universally supplemented via the existing exception process to reimburse facilities their costs. Almost exclusively facilities requiring increased reimbursement through this exception process are the hospital-based facilities. The proposed regulations with a prospective rate aim to change the exception process significantly. "We are proposing clarifications of both procedural requirements and the criteria for resolving exception requests. These procedures and criteria are designed to discontinue the practices followed in the past with respect to granting exceptions. Instead, we expect that under the proposal, few facilities would be able to qualify for exceptions to their payment rates."

Exceptions are to be allowed for facilities that: (1) have an atypical case mix; (2) are suffering from extraordinary circumstances; ie, secondary to natural disasters; (3) are isolated and are the only suppliers of dialysis in the geographical area; or (4) that have increased costs attributable to educational programs involving outpatient dialysis services.

The regulations make it quite clear that exceptions will be looked upon with disfavor and there has been a distinct shift such that the presumption will be that exceptions are to be denied. Thus, when Dr. Davis in her testimony acknowledged that there may be a sicker population of patients cared for by hospital-based facilities but that the exception process would allow for this, she has consigned those facilities to a process that is to be administered sparingly such that few would qualify.

It is anticipated that most exceptions will be sought under the category of atypical case mix. The difficulty with this process derives from the fact that there has been no definitional delineation as to what is a typical case mix from which atypical case mixes can be distinguished. One of the HCFA representatives testifying before the Subcommittee on Intergovernmental Relations and Human Resources admitted that this definition of atypical case mix is a problem and that HCFA will need time to determine what is atypical.

Furthermore, the exception process which will be established is likely to be one which will result in lengthy determinations before the ultimate decision to grant or deny the exception is made. This forces the facilities seeking the exceptions to bear the differential between the rates allowed and their costs until that issue is resolved. Obviously, this will result in putting such facilities in cash flow positions that would be untenable. Rather than risk the adverse outcome of the exception request and attendant appeals, many hospital-based facilities will be carefully scrutinizing their costs and initially making the determination of whether they can afford to continue to maintain their hospital-based outpatient programs in the face of the propsed regulations.

If such an eventuality were to occur and such programs became constricted in capacity or closed down entirely, one must ask what will happen to the patients currently cared for by such facilities? Those patients who are potentially unstable and who carry secondary diagnoses will have to be dialyzed at free-standing facilities. It must be anticipated that in such settings there will be less ability to tailor their dialysis treatments to adjust for their conditions and the complication rates will go up. This will result in increases in mortality and morbidity which will necessitate more frequent admissions of such patients to the hospital. As inpatients they will be dialyzed in the hospital at rates far in excess of what the same hospitals would receive if they were dialyzed as outpatients, in addition to the increased hospital costs of caring for them. In the face of such a scenario, one is tempted to ask whether this is an instance of the government being "penny-wise and pound-foolish"?

SUMMARY

In summary, the AAMC wishes to emphasize the following points:

The end stage renal disease program is not a cost-ineffective program, rather it is one which is providing services for an ever increasing population of patients;

The purpose of the proposed regulations to increase the use of home dialysis will actually be undermined by the regulations as they penalize hospital-based facilities, the chief source of patients dialyzing at home;

The rate structure established by HCFA is grossly deficient as it is one based on old, inadequate data used to establish a methodology which fails to carry out the Congressional directive for a dual rate structure and for which there is evidence that it was constructed to generate a predetermined savings, rather than reflecting an objective analysis of facilities' costs;

The proposed regulations refuse to recognize that hospital-based facilities care for a population of dialysis patients who are sicker and have greater potential to experience complications on dialysis than those dialyzed at free-standing facilities; and

The exception process established by the proposed regulations is one that looks with disfavor upon the granting of exceptions and will be inadequate to provide hospital-based facilities relief from the adverse effects of the propsoed rates.

Consequently, the AAMC strongly urges the Subcommittee to recommend that HCFA suspend its plans to implement the proposed regulations. Further, the AAMC urges the Subcommittee to restate and emphasize its previous position that HCFA develop a methodology for hospital-based dialysis which used up-to-date, accurate data and which accounts for the particular needs of hospitals and their patients in setting hospital payment rates.

Sincerely,

JOHN A. D. COOPER, M.D.

BETH ISRAEL HOSPITAL,
Boston, Mass., April 20, 1982.

JOHN J. SALMON, Esq.
Chief Counsel, Committee on Ways and Means, Longworth House Office Building, Washington, D.C.

DEAR MR. SALMON: The following letter contains comments which should be included in the hearings record for the hearing on proposed reimbursement rates for end stage renal disease (ESRD). It is my intent to present data which will show that hospitals like the Beth Israel provide ambulatory dialysis to a patient population which cannot be handled by the independent facilities, and to show that these patients are not appropriate candidates for home treatment, thereby justifying the higher costs of some hospital based units which are explained by higher staffing ratios and burdensome overhead allocations.

It should first be pointed out that there are two different types of hospital based facilities. The first treats ESRD patients on a nonselective regional basis. These units are somewhat similar to the independent facilities in the types of patients in their case mix. The second (Beth Israel being an example) refers out all stable ESRD patients to the lower cost independent facilities for treatment or home training and retains only those patients whose medical conditions warrant hospital based dialysis. We feel that if units like ours are to survive, and there is a large population of patients whose continued existence depends on units like ours, that this critical difference in patient populations must be specifically recognized by the regulations. We request that the regulations specify that hospital based units which can document that they refer all stable ESRD patients out to independent facilities and retain only unstable patients will be granted an exception to the rate screen.

It is the present position of HCFA that there is no major difference between the ESRD patient being cared for by hospitals like Beth Israel and those being cared for by the independent facilities. The Health Care Financing Administration points out that the medical conditions and complications are similar for both sites. What this position fails to take into account, however, is the status of the patient and the patient's functional capacity. Within every medical diagnosis code there is a group of patients which is stable and a group which is seriously ill. Using Beth Israel's current ESRD patients as an example will illustrate this point.

(1) Our patients are considerably older. As of March 1, 1982 the median age of the 31 patients in our hospital based dialysis unit was 69, compared to a median age of 61 for the 81 Beth Israel patients who have been referred out to an independent facility where they are still receiving ESRD care as of March 1, 1982. The average age for all patients in our ESRD Network (#28) is only 52.

(2) Of the 31 patients presently receiving dialysis at Beth Israel Hospital, 13 are "bounce-backs," patients who have been previously referred to independent facilities for treatment or home training but have been sent back to Beth Israel because of complications requiring care which could not be provided by the independent facility. The 13 complications are as follows:

a. Clotted artificial arterio-venous fistula requiring repeated femoral vein catheterizations or dialysis.

b. New cerebral stroke, increasing congestive heart failure and weight loss.

c. Severe back pain and missing dialysis treatments. (It is common practice for the independent facilities to return patients to hospital based centers when they frequently miss dialysis and thereby contribute to a loss of charges. We should point out our concern as to what will be the fate of such patients with psychological difficulties that often cause them to be difficult treatment problems.)

d. Severe headaches and psychological reasons.

e. Increased debilitation, frequent vomiting, diarrhea and medication intolerance.

f. Bacterial septicemia and ruptured arterio-venous fistula with hemorrhagic shock.

g. Brain trauma with epidural and subdural hematomas causing confusion.

h. Multiple episodes of unconsciousness, seizures and cardiac arrhythmias.

i. Weight loss and intractable severe itching during dialysis.

j. Myocardial infarction and cardiac disease.

k. Systemic lupus erythematosus with pericarditis, pericardial effusion and poorly functioning and clotting AV shunts and fistulae.

l. Malignant hypertension and hyperkalemia.

m. Left leg tibial fracture and fever secondary to cholangitis.

Thus, as of March 1, 1982, 40 percent of our dialysis patients were returnees from independent facilities that were not capable of managing the patients' medical problems. The remaining 60 percent of our population is represented by patients who could not be referred out because of continuing unstable medical conditions and a small number of patients who are awaiting placement to an independent facility. Moreover, these percentages do not represent an aberration. A review of our dialysis patients for the period January 1, 1980 thru February 28, 1982 reveals that of a total of 183 patients, 55 were "bounce-backs" for various medical conditions requiring hospital based care.

(3) Most independent facilities are able to function with their patients in chairs during dialysis. In facilities like ours, almost all patients are dialyzed in beds. This choice is not merely the result of habit. The use of beds is conditioned by an increased incidence of severe hypotensive shock, seizures, and cardiac arrhythmias which occur in our hospital based patients. Additionally, many of our patients require costly and labor intensive equipment such as cardiac monitoring, not normally found in the independent units and certainly not found in a home based situation.

The rate setting methodology also seems to be inappropriate and unfair in our situation since it assumes that all facilities will seek to maximize the number of treatments provided in the patient's home in order to lower the facilities' average cost per treatment. As previously stated, our facility retains only unstable patients who are unsuitable for an independent facility or in-home dialysis and has no opportunity to take advantage of this technique.

We foresee little ability for providers like the Beth Israel to adapt to the proposed new rates. If the rates are effective June 1, 1982, we project a fiscal 1982 gross violation for Beth Israel of $300,420. The picture becomes even more disastrous when projected for fiscal 1983 when Beth Israel's gross violation would increase to $467,300.

Should the prospective reimbursement rates be implemented as proposed, hospitals like Beth Israel will have no choice but to seriously consider discontinuing the provision of ambulatory dialysis. No cost based health care facility can withstand losses of the magnitude we project for such a small program. The effect of this program's loss on other hospital programs will be intolerable. But what is the alternative—the independent facilities cannot and will not care for these patients. Not only are the independent facilities not competent to provide the care, they are not in business to lose money for their stockholders. What will happen to these patients? Where will they go for treatment?

Sincerely,

DAVID DOLINS,
Executive Vice President and Director.

HARVARD MEDICAL SCHOOL, BETH ISRAEL HOSPITAL,
Boston, Mass., April 28, 1982.

Mr. JOHN J. SALMON,
Chief Counsel, Committee on Ways and Means, Longworth House Office Building, Washington, D.C.

DEAR MR. SALMON: I am taking this opportunity to provide a letter of testimony to be enclosed in the hearing record for your hearing on Proposed Regulations governing reimbursement under the End-Stage Renal Disease Program. The proposed regulations were described by the Department of Health and Human Services, Health Care Financing Administration, 42 CFR Part 405, "Medicare Programs; End-Stage Renal Disease Program; Prospective Reimbursement for Dialysis Services" as published in the Federal Register, Volume 47, Number 30, Friday, February 12, 1982. I am a physician practicing in the subspecialty of Nephrology, caring for patients with end-stage renal disease who receive dialysis treatments as outpatients in a hospital unit, in several independent facilities, and at home. I have no proprietary interest in any hospital or dialysis facility and I have had considerable experience in the care of dialysis patients since 1969. My comments about the proposed rule changes for prospective reimbursement for outpatient dialysis will first relate to the providing facilities and then discuss physician services for dialysis patients.

In regard to the prospective reimbursement of dialysis facilities, the proposed rules establish a dual rate, one for hospital-based facilities and one for independent facilities, each rate set at the median level of the allowable costs of all such facilities, weighted for the percentage of patients of the hospital-based or independent facilities dialyzing at home to formulate a composite rate which is then adjusted for geographic wage differences. While the major goal of the prospective reimbursement rates is to create a strong incentive for hospital-based and independent facilities to dialyze as many patients in the home as possible, the single rate structure for all hospital-based dialysis facilities is an unrealistic oversimplification. It must be pointed out that there are two different types of hospital-based facilities. The first type treats ESRD patients on a non-selective regional basis so that these units are in many ways similar to the independent facilities in the types of patients in their case mix. The second type of hospital-based facility, of which the Beth Israel Hospital is one, refers stable ESRD patients out to lower cost independent facilities for treatment or home training and retains only those patients whose medical conditions warrants outpatient hospital-based dialysis at a greater cost. Since there is a significant and growing proportion of dialysis patients who are older, sicker, and have been referred back to hospital-based facilities from independent facilities (because of medical problems inadequately cared for by these independent facilities, often requiring multiple ambulance transfers to hospital emergency rooms for complications occurring during dialyses), it is essential that units such as ours are permitted to survive. Although the regulations permit an exception for atypical patient mix, it is essential that this critical difference in case mix at hospital-based dialysis facilities be recognized specifically within the regulations. I would suggest that the regulations be modified to guarantee that hospital-based dialysis facilities which document that they refer all stable ESRD patients out to independent facilities and retain only unstable patients be granted an exception to the proposed rate, based on their allowable costs. Clearly the rate setting methodology as it is currently constructed would be inappropriate and unfair to such facilities. Since that rate setting methodology assumes that all facilities will seek to maximize the number of treatments provided in the patient's home in order to lower the facilities average cost per treatment, it must be recognized that such hospital-based facilities which retain only unstable patients who are unsuitable for transfer to an independent facility will obviously be unsuitable for home dialysis and therefore such facilities have no opportunity to take advantage of the proposed incentive in the new rates.

In support of such a position by hospital-based units caring for more complicated patients, I offer the following arguments. It is the present position of HCFA that "we conclude, therefore, that with respect to these measures of patient need, there is no great difference between hospital-based and independent facilities" (page 6564). The Health Care Financing Administration bases this position on examination of the age, sex, race and utilization rate (discharges and days of care) differences between hospital-based and free-standing facilities, suggesting that the data which is available to them through the Medical Information System does not support the claim by hospital units that such units "treat more patients with multiple conditions or other complications". In fact, the data obtained by the Medical Information System, which includes the above information, doesn't include the medical condition or other complications of patients with ESRD. Therefore, such data are neither adequate to, nor designed to, provide conclusions about the "multiple conditions or other complications". Moreover, what the HCFA position fails to take into account, is that the status of a patient may often be determined less by his medical diagnoses and more by his functional capacity. Therefore, within every medical diagnosis code there is a group of patients which is stable and a group which is ill. Moreover, it is not clear that the Medical Information System has provided adequate data to delineate the group of hospital-based facilities which utilize a referral pattern that does treat such medically complicated patients. Using the Beth Israel Hospital's current ESRD patients as an example will illustrate this point.

1. Our patients are considerably older. As of March 1, 1982 the median age of the 31 patients in our hospital-based dialysis unit was 69 years, compared to a median age of 61 years for the 81 Beth Israel hospital patients who have been referred out to an independent facility where they were still receiving ESRD care as of March 1, 1982. Moreover, the average age of all patients in our ESRD network (#28) is only 52 years.

2. Of the 31 patients presently receiving dialysis at Beth Israel Hospital, 13 are "bounce-backs", patients who have been previously referred to independent facilities for treatment or for home training but who have been sent back to the Beth Israel Hospital because of complications requiring care which could not be provided by the independent dialysis facility. The 13 complications are as follows:

a. Clotted artificial arterio-venous fistula requiring repeated femoral vein catherization for dialysis.

b. New cerebral stroke, increasing congestive heart failure and weight loss.

c. Severe back pain and missing dialysis treatments (it is common practice for the independent facilities to return patients to hospital-based dialysis centers when they frequently miss dialysis and thereby contribute to a loss of charges. I should point out my concern as to what will be the fate of such patients with psychological difficulties which often cause them to be difficult treatment problems.)

d. Severe headaches and psychological reasons.

e. Increased debilitation, frequent vomiting, diarrhea and medication intolerance.

f. Bacterial septicemia and ruptured arterio-venous fistula with hemorrhagic shock.

g. Brain trauma with epidural and subdural hematomas causing confusion.

h. Multiple episodes of unconsciousness, seizures and cardiac arrhythmias.

i. Weight loss and intractable severe itching during dialysis.

j. Myocardial infarction and cardiac disease.

k. Systemic lupus erythematosus with pericarditis, pericardial effusion and poorly functioning and clotting A-V shunts and fistulae.

l. Malignant hypertension and hyperkalemia.

m. Left leg tibial fracture and fever secondary to cholangitis.

Thus, as of March 1, 1982 40 percent of our dialysis patients were returnees from independent facilities that were not capable of managing the patient's medical problems in an optimal fashion. The remaining 60 percent of our population is represented by patients who could not be referred out because of continuing unstable medical conditions and only a small number of patients who are awaiting placement to an independent facility. Moreover, these percentages do not represent an aberration present on March 1, 1982. A review of our dialysis patients for the period January 1, 1980 through February 28, 1982 reveals that of a total of 183 patients cared for at our facility, 55 were "bounce-backs" for various medical conditions requiring hospital-based dialysis care. Thus, regardless of the claim by independent facilities and HCFA, the above data support a conclusion that there are indeed differences between the case mix of patients in hospital-based units such as ours and those of independent facilities.

3. Most independent facilities are able to function with their patients in chairs during dialysis. In facilities like ours almost all patients are dialyzed in beds. This choice is not merely the result of habit, as we recognize that chairs would allow a more optimal use of space. The use of beds is conditioned by an increased incidence of severe hypotensive shock, seizures and cardiac arrhythmias which occur in our hospital-based dialysis patients. Additionally, many of our patients require costly and labor-intensive equipment such as cardiac monitoring, ventilation support, etc. not normally found in the independent units and certainly not found in a home-based situation.

The foregoing data offers a strong argument that some hospital-based dalysis facilities are indeed offering care to patients with multiple conditions and more elderly that is more costly and should be recognized within any proposed regulations. There must be room within the reimbursement system to recognize such "tertiary care" type of dialysis facilities in the same manner that the need for tertiary care hospitals for inpatients has been clearly recognized. As a physician, I am concernced that the prospective reimbursement rates, if they are implemented as proposed will cause hospitals like the Beth Israel to have no choice but to discontinue the provision of ambulatory dialysis. If they do, what will be the alternative mode of care for my patients with these complications? The independent facilities are not competent to provide such optimal care, nor will they be interested to do so under the prospective rate screen which will only serve to diminish their ability to remain financially solvent. In our desire to save money, we must not forget about these patients.

It is known that physicians like myself who care for patients both at hospital-based and independent dialysis facilities do not refer our patients arbitrarily. Instead we consider their medical condition to differentiate those requiring the greater care capabilities of the hospital-based facility to make this choice. Thus, one may question the adequacy of the rate setting methodology. In computing a composite rate HCFA used a factor based on the proportion of the patients dialyzing at home versus in-facility for hospital-based units and for independent units to arrive at the final two rates. However, since a unit such as the Beth Israel Hospital refers all stable patients to other facilities who later train a percentage of these patients for home dialysis, our hospital-based facility retains only those patients that are not suitable for training for home dialysis. I have already pointed out above that our unit will clearly suffer under this method of rate sturcture. Moreover, the regulations never delineate whether patients who were referred from our facility for home training at an independent facility might then be returned to us for billing as one of our home patients. I am quite sure that the independent training facility would object to such a scheme, since that would potentially remove all hospital referred patients from their home dialysis rosters. On the other hand, the rate structures are certainly not fair to our unit which would always have no home dialysis patients (unless we want to initiate an unneeded home dialysis training program to benefit from this aspect of the rate setting methodology). It is important that the regulations clarify which facility is allowed to bill for a patient referred from a hospital facility to another facility for home training. Since both facilities will probably be eager to provide back-up care, the rate structure must provide for this in a equitable manner.

I am also concerned about the method of utliizing the median cost per treatment to set up a single rate system. This method seems to be based on an assumption that half of the units are functioning inefficiently and should be able to reduce their costs to the level of the median. I doubt that this arbitrary assumption by HCFA can be documented, nor do I think that it makes sense. I am also concerned, as a physician, about the results of utilizing such an accounting method. It will force half of the units with costs above the median to cut costs so as to avoid losses. Since overhead and fixed costs are difficult or impossible to reduce, these units will diminish their costs in ways that may adversely impact on patient care. For example, I foresee the possibility that such units will allow only certain dialyzers (the cheapest obtainable under large purchasing contracts) to be used, regardless of the needs of a minority of patients that might benefit from different types of dialyzers (that might be more expensive), and may minimize labor levels below that required for safety and patient comfort. Our hospital-based unit is already faced with the care of patients that cannot properly be managed at the low cost of independent facilities and who require a higher staff to patient ratio. I am concerned that hospital-based units that care for such patients will remain unable to get their costs below the new rate and maybe induced to curtail this acitivty. Independent facilities which operate for profit will not be able to dialyze such patients and stay below the median of costs. Moreover, both hospital-based and independent dialysis facilities will not continue to be willing to dialyze patients with psychological conditions that make them difficult to manage or who miss dialysis appointments, causing a loss of supplies set up for dialysis without a charge for the procedure. If hospital-based dialysis facilities are not available to care for these patients at higher costs, I am afraid that we may go back to the past when patients with treatable ESRD were allowed to die because of inadequate dialysis facilities. It must be assumed that many facilities operating at costs above the median can do so because such costs are justified. I strongly urge that the proposed regulations allow for rates set at a higher level than that of the median facility within each type (possibly the 80th percentile would be reasonable).

Another concern is whether rate adjustments will continually be made to the median of the costs of the previous year sustained by either hospital-based or independent facilities. If the prospective rate is continually set at the median and all of the units with costs above the median attempt to reduce them to levels at or below the median level of the year before, it seems likely that within a short period of time all dialysis will have to be performed in a relatively uniform manner using the cheapest supplies available and minimum level of staffing. What provisions are there to enable the innovation of new dialyzers, new supplies or techniques that may offer an advantage to patient care but maybe more expensive (or even new techniques which may eventually offer cost saving when mass produced, but are more expensive initially)? Even more, what provisions are there in the proposed regulations that will ensure that the cheapest means of dialysis are adequate and safe for all patients in each facility?

Second, I urge reconsideration of the proposed rate setting methodology for physician capitation payments. HCFA's proposed rate establishes equal monthly capitation payments for both home and in-facility dialysis presumably in an attempt to offer an incentive to physicians to send patients home (or at least obliterate any financial incentive to retain them in a facility). HFCA also porposes revision of the basis for the capitation payment so as to decrease the overall payment to physicians carrying an average proportion of in-facility and home patients. Moreover, once the physician rate is set by this methodology it will be held constant rather than automatically updated by the carriers' pervailing charge data. Several major discrepancies in reasoning and methodology seem to be inherent in this proposal.

(1) Proposing equal payments for home and in-facility patients despite the obvious difference in the physician's time and effort in the greater care needed for in-facility patients is unfair and illogical. This method assumes that physicians are current-

ly placing patients in facilities because of the increased reimbursement that they receive, rather than using home dialysis if the payments were to be equal. This argument seems fallacious in two ways. The percentage of patients dialyzing at home is quite different in different geographical areas of the country. This suggests that the patient's cultural and home setting plus local physician experience may explain these differences in home dialysis percentages, rather than any financial motivation from HCFA which would be similar over the entire country. Also, a recent attempt to show that the home dialysis patient percentage was lower in areas with more independent facilities operating for profit failed to document such a significant correlation (New England Journal of Medicine 304:996–998, 1980). Perhaps more important is the argument that should financial incentive be improperly swaying physicians to maintain patients within facilities, the attempt to buy off such physicians would presumably induce this type of doctor to send patients home who should not be performing home dialysis and to hospitalize patients who do not require hospital admission. It is insulting to propose this type of bribe to most honest physicians and it will backfire in the case of the few unscrupulous ones.

(2) Physicians who are caring for the sickest dialysis patients in hospital-based units that retain only patients who need close supervision and cannot be trained to perform dialysis at home are unjustly being penalized by the proposed regulations. These regulations have an adverse effect on the income of such physicians without any counterbalancing legitimate benefit that justifies the method. If one wanted to use a financial carrot to enhance home dialysis, it would be appropriate to increase the home dialysis physician capitation rate to the level of the in-facility dialysis rate, rather than to decrease the latter without any suggestion that the current rate is set too high for the service rendered.

(3) In the rate setting methodology a figure of 12.4 dialysis sessions per patient per month is used as the base multiplier to be applied to a brief office visit charge in order to determine the physician capitation fee. This base multiplier assumes that the physician will see the patient only during each dialysis session but does not allow for any other aspects of patient management during the month, such as other office visits, emergency room visits, telephone calls, and transplantation evaluation sessions with patient and family that should be factored into this rate in a capitation system covering all aspects of care.

(4) The physician's capitation fee has changed only minimally since 1972. It has not come close to keeping pace with the inflationary changes during that period of time or with the prevailing rate changes for other services rendered by physicians. The major reason for HCFA's concern over the increase in total physician payments is based on an increase in total numbers of dialysis patients and an increase in the number of nephrologists caring for such patients. The proposed reduction in the capitation fee paid to physicians for in-facility care, which is not adequately compensated for by the small increase in the fee for care of home dialysis patients, will have an adverse impact on the income of most nephrologists which is unfair and unjustified. I suspect the most conscientious physicians will not be motivated to care for dialysis patients and only physicians who give less time to their patients will practice successfully under this rate screen. The result of this proposal must have an adverse impact on patient care, particularly the most complicated and ill in-facility patients, which may result in higher inpatient hospital days and increased costs in the long run.

(5) There is no rationale offered for the failure to update the physician capitation fees with the carrier's prevailing charge data. This is certainly unfair to physicians caring for dialysis patients as a group who are not exempt from the effects of inflation upon their own costs, overhead and income needs. The fact that HCFA is attempting to reduce physician reimbursement at a time of rampant inflation already shows that they have no concern for the physician. The HCFA proposal that "the rate would only change when, after review of the rates, we determine that the data justifies an update" is arbitrary, prejudicial and unreasonable.

For the foregoing reasons, I ask that the physician's capitation fee for patients dialysis in a facility be left at its current rates, or consideration be given to increasing this rate to adjust for inflation over the past ten years, whether or not the physician's fees for patients dialyzed at home is increased up to a higher level. Moreover, these fees ought to be updated according to the prevailing charge data in a similar manner to physician fees in other areas of medical practice.

The goal to minimize costs for dialysis services and physician services to dialysis patients is laudable. However, the prospective reimbursement rates as proposed by HCFA seems arbitrary and prejudicial in a negative way to patient care of this chronically ill and deserving segment of our population. Nowhere in the regulations is there any proposal to guarantee that a minimal level of quality will be maintained by dialysis facilities which are willing to dialyze patients at the median rate proposed. Nowhere in the regulations is there concern for a minimal level of quality of care to be received by patients from physicians who are willing to care for them at the proposed low rates. Nowhere has the question of fairness been considered as there is no suggestion, much less documentation, that the facilities with costs above the median are benefiting unjustly or that physicians caring for such patients are being overpaid. The proposed regulations, in respect to reimbursement of hospital-based facilities and physician fees for patients dialyzed in these facilities, represent an unjustified way to economize and ought to be modified or rescinded as outlined above. I thank you for the opportunity to comment on these actions.

Yours truly,

ROBERT S. BROWN, M.D.,
Clinical Chief, Renal Unit,
Associate Professor of Medicine.

APRIL 21, 1982.

To: Ways and Means Oversight Sub-Committee, c/o John J. Salmon, Chief Counsel, Committee on Ways and Means, 1102 Longworth House Office Building, Washington, D.C. 20515.

From: Allen R. Nissenson, M.D., Director—Dialysis Program, UCLA Center for Health Sciences, Los Angeles, Calif. 90024.

Subject: Proposed Reimbursement Rates for the End Stage Renal Disease Program (Federal Register 47:6556-6582, February 12, 1982).

I believe that the proposed reimbursement regulations should be withdrawn and revised for several reasons:

(1) Cost data gathered by HCFA to date is limited and inaccurate. The proposed rates are so low that higher cost, primarily hospital-based facilities may be forced to stop providing out-patient dialysis services. Since the majority of home dialysis programs are also run through hospital-based facilities, this may result in the opposite of HCFA's intent—that is, the very facilities that are doing the majority of home dialysis may be forced out of the dialysis business. The result will be less, not more home dialysis.

(2) HCFA is promoting "home dialysis" but has no cost data to assess its supported monetary savings. To legislate medical practice this way, even to control costs, with little or no data is deplorable.

(3) Though the concept of composite rates is appealing, the higher cost of hospital-based dialysis must be taken into account in the actual rates set. This should include a local wage index for workers in the dialysis field, not a general wage index. In addition HCFA cost data showed a much greater difference in costs between hospital and independent facilities than appealed in the proposed regulations. The rates should, therefore, be adjusted to reflect the actual cost data HCFA has, imperfect though it may be.

(4) The 100 percent reimbursement for home dialysis equipment unquestionably should be maintained. By rescinding it, another disincentive to home dialysis is created.

(5) HCFA must adjust reimbursement rates annually based on inflation since this truly reflects increased cost to the provider.

(6) The cost of home dialysis training (primarily CAPD) at UCLA is $272 per session. Under the proposed reimbursement rates we will be receiving only $161 per session. This will make it impossible to continue home dialysis training at our institution. We presently have over 50 CAPD patients, the largest such group in southern California. The proposed regulations will definitely adversely effect our home dialysis program.

(7) Teaching institutions like UCLA must be able to continue to provide dialysis. We not only provide the very best care to our patients but carry out clinical research activities to advance the field of dialysis and for which we must have a reasonable cadre of patients. Home training programs for CAPD and renal transplant programs are centered in teaching hospitals as well and are inextricably entwined with provision of out-patient dialysis. It is essential to permit such institutions cost reimbursement since increased costs are truly legitimate. Though the proposed exception process mentions "costs of education" this is quite vague. It would be acceptable if HCFA had precise data on such costs in several teaching institutions. We would be happy to provide such data from our own institution.

In summary, the proposed reimbursement regulations are based on insufficient cost data and unfairly penalize hospital-based facilities. If adopted these regulations will result in closing of numerous hospital-based units, many of which provide the bulk of home dialysis training. Home dialysis can only suffer as a result. The cost impact of a large CAPD population has not been carefully studied—a complete HCFA audit of CAPD costs should be performed before promoting this form of dialysis so heavily. Unless reimbursement for home training is increased, home training programs such as ours will be unable to survive.

STATEMENT OF DIALYSIS CLINIC, INC., BY J. M. GRISSIM, COUNSEL

SECTION I.—IDENTITY OF PROVIDER—DIALYSIS CLINIC, INC.

Dialysis Clinic, Inc. (hereinafter referred to as "DCI") is a not-for-profit corporation which began treating E.S.R.D. patients in 1971, two years before reimbursement was available through Public Law 92-603.

The corporation currently provides care to 1348 E.S.R.D. in-center patients (541 white and 807 non-white), and 350 home-trained patients in 22 centers located mainly n the southeast except for five units located in Pennsylvania, Ohio, New Mexico and Missouri.

DCI affiliates itself with the nephrology division of medical schools where possible. The nephrology staff of the medical school assumes full responsibility for direction of patient care and DCI assumes the responsibility for administrative functions within the facility. Currently, such arrangements exist with nephrologists in the medical schools of the following universities: Vanderbilt University, Emory University, University of Missouri, University of Cincinnati, University of New Mexico, University of Kentucky, and University of South Carolina.

All physicians attending patients in D.C.I. centers are paid by the Alternate Reimbursement Plan. The physicians, generally, as faculty members of the above medical schools, are subjected to private practice plans of the particular university or their salaries are monitored by the university.

The medical directors are compensated as follows, based upon the number of dialysis stations in the unit: 30 or more stations—$2,070.00 per month; 20 or more stations—$1,725.00 per month; 10 or more stations—$1,150.00 per month; and less than 10—$575.00 per month.

D.C.I. has sponsored and/or participated in the research programs related to E.S.R.D., as set forth in Exhibit "A" attached hereto and incorporated herein by reference.

The corporation by its stated Charter and its record of performance exists to serve the E.S.R.D. patient.

In-center home dialysis and kidney transplants are considered each according to the best interest of the patient. At the present time twenty (20 percent) percent of our total patient population is dialyzing at home.

DCI actively supports the kidney transplant program in Nashville, Tennessee, where 96 transplants were performed in the calendar year ending December 31, 1981.

The Corporation sponsors and supports the organ procurement programs in Tennessee and in Atlanta, Georgia.

SECTION II.—EFFECT OF PROPOSED RULES TO DCI AS A PROVIDER

The following table demonstates the impact of applying the proposed rules to each of the DCI dialysis facilities. Column No. 1 lists the cost per dialysis treatment for the fiscal year 1981; Column No. 2 shows the amount which would have been paid by Medicare for the treatment in 1981 if the proposed regulations were in effect (not including Medicaid, State Renal and private insurance).

These figures, projected into 168,488 dialysis procedures performed in all centers for the fiscal year 1981, indicate an average revenue decrease of $16.35 per dialysis procedure, for a gross reimbursement rate of $121.65 per procedure (with Medicare to pay 80 percent of $121.65 or $97.32), in lieu of the $128.00 gross rate per procedure stated as the HCFA "national rate" in the proposed regulations.

	Cost per dialysis for year 1981	[1] Amount paid by medicare under new regulation
Albany, Ga.	$113.62	$92.88
Aliquippa, Pa.	297.94	103.82
Atlanta, Ga.	143.92	95.30
Charleston, S.C.	112.95	97.67
Chattanooga, Tenn.	133.40	99.59
Cincinnati, Ohio	124.70	101.96
Columbia, Mo.	145.05	105.54
Corbin, Ky.	157.61	91.47
Crawford Long, Ga.	122.04	95.30
East Ridge, Tenn	135.05	99.59
Jackson, Tenn.	135.91	89.93
Jacksonville, Fla.	130.04	95.98
Kirksville, Miss.	137.06	91.29
Knoxville, Tenn.	122.93	95.04
Lexington, Ky.	133.74	94.70
Low Country, S.C.	153.92	97.67
Madison, Tenn.	121.40	99.43
Morehead, Ky.	171.86	91.47
Nashville, Tenn.	113.56	99.43
Spartanburg, S.C.	139.98	96.14
West Peachtree, Ga.	247.81	95.30

[1] Does not include medicaid, State renal, or private insurance.

SECTION III.—COMMENTS

A. In general

DCI supports the concept of conservation of our national resources to the extent that the quality of patient care or human life is not sacrificed for economic austerity. The burgeoning cost of the E.S.R.D. program, however, is not due to provider inefficiencies. Rather, it is due to the increasing number and longevity of existing patients, and is actually a measure of how effective the program has been, since its inception, in making available appropriate therapy for the E.S.R.D. patient. The modality of treatment whether it be hemo dialysis or C.A.P.D. home dialysis, in-center dialysis, or transplantation, should continue to be dicated solely by the best interest of the individual patients.

Although we appreciate the concern for cost containment, we feel that the regulations, as promulgated in the February 12, 1982, edition of the Federal Register, do not fairly distribute the burden of cuts among the nation's E.S.R.D. providers. We question the methodology of the regulations and suggest that a more equitable fashion of cost reduction might be obtained through a modification of criteria.

To assure ease of reference, we will address our comments separately to the labor and non-labor components of the proposed regulations.

B. Patient care considerations

As a result of DCI's continuing interest in the way in which end-stage renal disease patients receive care, the new proposed regulations are of particular concern for what they may do to the E.S.R.D. patient's access to care and to freely choose between various modes of therapy.

The marked, proposed reduction in reimbursement for dialysis treatments in-center may well cause many facilities to adopt stringent cost saving measures to stay in business.

The patient with complicated illness who requires significantly more care than a stable dialysis patient without complicating illness, may find it mare difficult to locate a facility in which to dialyze because that facility may no longer be able to allocate the additional patient care personnel required to take care of such a complicated patient. With similar decreases in reimbursement for in-hospital facilities and more stringent requirements for the exception process, hospital facilities likewise may be less willing or less able to meet the needs of these more complicated, end-stage renal disease patients. This likely consequence of the proposed regulations needs to be appreciated by those promulgating the regulations before they become final.

There is nothing in these proposed regulations to stimulate access to transplantation. Quite the contrary, it is quite conceivable that access to transplant will be even more limited under these new regulations than is currently the case under the old. Under the proposed regulations, the hope is extended that a facility and the physician can make money through the care of home-dialysis patients. By establishing the regulations in this manner, it was hoped by the regulators that such an arrangement would stimulate increased utilization of home-dialysis. But it is generally these more stable, home-dialysis candidates who are also candidates for transplantation. If, in fact, a unit's only hope for solvency should rest with the maintenance of a large group of home-dialysis patients, there may be even more hesitation than in the past to allow these patients to be referred for transplantation.

It is conceivable, under these circumstances, that sequestration of patients away from the opportunity to make a free and informed choice regarding the option of transplantation may be the unintended result of the stingent economic pressure placed upon dialysis facilities by these proposed regulations. It is ironic that such a disincentive towards transplantation may occur just at the time that improving graft survival and decreasing mortality following transplantation are at last being documented.

One can only wonder if these above-mentioned, significant alterations in patient care were the true intent of Congress in the passage of the Omnibus Reconciliation Act. One would hope that economies can be realized in the end-stage renal disease program without involving the hazard of interruption of access to treatment by certain patient groups or impairing the patient's free choice of the mode of therapy for his or her end-stage renal disease.

C. Labor cost component of proposed rate

The labor cost component of the proposed reimbursement rate is based on a national figure, as adjusted by local averages. The national figure is calculated according to salary figures from all hospital personnel, listing not only nurses but dishwahers, laundry workers and housekeepers as well. The staff of a dialysis facility consists of a much larger percentage of professional patient care personnel than a typical hospital staff. We suggest, therefore, that the labor cost component be adjusted upward to allow for the real cost of professional personnel.

Furthermore, the wage price index seems to be an inadequate measure upon which to guage changing labor costs within a dialysis facility. The actual wage scale of the professional staff employed in a dialysis center is not accurately reflected by the wage price index. It would seem more appropriate to devise the labor cost component from actual statistics from existing dialysis centers. Surely there are currently enough dialysis facilities available from which to obtain this data.

D. Nonlabor composite cost component of proposed rate

The proposed regulations erroneously assume that inflation has not affected dialysis costs over the years. Since reimbursement by Medicare, DCI investigations indicate that the composite costs of medical care have increased over 90 percent while the screen has remained constant. Inflation affects dialysis facilities in areas of medical supplies, insurance, equipment, construction, property (real or personal), utilities, and service contracts. Many of our essential supplies are petroleum-based products and rise, but do not necessarily fall, with the fluctuation of oil prices.

Medical supplies comprise one of the two largest areas of cost (salaries the other). In many of our facilities, the cost of medical supplies surpasses 40 percent of the revenue. Costs of many disposable items, such as syringes and needles, have risen over 30 percent since 1980. A dialysis machine which cost $6,500 in 1980 now approaches or exceeds $8,000 in cost. Recent deregulation of the trucking industry has spiralled the cost of concentrate, saline and other liquids, which are now expensive to ship. The cost of a 50-gallon drum of concentrate (standard formula) has increased by a third.

The cost of medical supplies plays an important role in home care as well. Peritoneal (C.A.P.D.) dialysis, increaingly the modality of preference for home patients, is a more expensive form of treatment. The regulations should take into account the higher expense of this modality of treatment. For example, DCI home trained 164 patients in 11 months of 1981—105 were C.A.P.D.; 33 were peritoneal; 26 were hemo.

Apparently, the proposed regulations were calculated on predominantly hemo home dialysis costs. Since that time, C.A.P.D. has become the predominant modality of treatment, outnumbering hemo training by 4 to 1. A recalculation of home dialysis costs using updated data regarding the proportion of home patients treated with each form of dialysis is important to accurately reflect today's home dialysis costs.

SECTION IV.—SUGGESTIONS

A. Review exceptions for reductions

HCFA should review existing exceptions for providers, disallowing all except for those providers who can justify an exception to the screen by corroborated medical evidence indicating that they are dialyzing patients whose disease is complex and requires a degree of medical effort exceeding that normally required for chronic maintenance dialysis patients. An exception should continue only to the extent that the provider's direct cost attributable to the treatment of such complex patients is increased.

B. Consider the effect of placing a limit on reimbursement for labor and supplies

DCI respectfully submits that the proposed reimbursement formula which places a cap on labor cost and supply cost, which is presently below the actual labor and supply cost, must foretell serious detriment to the patient.

C. Retain screen

Although we understand that composite rate reimbursement has been mandated by Congressional action, it bears consideration that the proposed rule may in fact increase the costs of the E.S.R.D. program. One of the basic premises of the proposed rule is that facilities will be able to survive by requiring patients to go on home dialysis.

It is likely that labor will be the area where facilities will attempt to cut costs in order to survive under the proposed rule. In instances where the number of skilled personnel is diminished, the remaining personnel will be less able to help patients who are having difficulty during a dialysis session because their attention will be spread over a larger number of patients and their capacity diluted.

With reduced labor, facilities will presumably be more fearful of having marginal patients undergoing dialysis, as will the physicians. They may therefor be more apt to refer those patients to hospitals for inpatient acute treatment. Without question, a patient who has to be admitted to a hospital as an inpatient to receive dialysis treatments will be more costly to the Medicare program than will a patient who is part of an adequately staffed outpatient facility.

DCI recommends that the screen be maintained in lieu of the proposed composite rate until current data for labor and nonlabor costs in dialysis facilities and for home dialysis is obtained.

D. Eliminate network and designate one intermediary nationwide

DCI further recommends that the administration of the program could be reduced by eliminating the network system and appointing one intermediary to handle E.S.R.D. claims nationwide.

E. Delay in implementing final regulations

Regardless of the outcome of the regulations' implementation, the transition from old to new will invalue a significant impact upon the mechanics of how 70,000 patients with E.S.R.D. receive care. Some facilities likely will close due to the economic pressures. Hospital facilities may be found to relocate, due to decreased reimbursement, to a free-standing facility. Facilities that try to stay open will have to alter the way in which care is delivered to their patients. An adjustment period between the time the final regulations are published and their implementation, we believe to be highly desirable, to avoid the potential disruption of patient care. In addition, an interim period between the regulations' final publication and their implementation would provide a buffer period through which the intermediaries and facilities alike could readjust to new billing requirements. Varied rates within one intermediary's jurisdiction will necessitate new criteria for billing, reporting, etc. Facilities will need time to adapt their bookkeeping practices and computer programs to meet the new guidelines.

Perhaps the most effective and efficient manner of dealing with this would be to have a single agent serve as intermediary for all providers.

EXHIBIT "A"—RESEARCH SPONSORED RELATIVE TO ESRD

Albany, GA:	
October 1981—No. 80 partial support of P.A. to do research work for OCI and work on kidney procurement	27,500.00
December 1981—No. 66A extension of previously approved project for promotional materials	500.00

1980-81—Purchase educational materials for promotion of organ procurement program. Clark	500.00
Atlanta:	
1977—Support of research unit	....
April 1978—Study on nephrectomized dog	4,000.00
April 1978—Study on anephric dog	5,000.00
April 1978—Furosemide and ultrafiltration	10,000.00
June 1978—Evaluation of nephgel	5,000.00
February 1979—Study of serum CPK and CPK isoenzyms	6,000.00
July 1977—Relative influence of potassium and intravascular volume	6,750,00
1980-81—Immunological effects of blood transfusion in rhesus monkeys	1,000.00
1980-81—Kinetics of intraperitoneal insulin during CAPD	4,500.00
Charleston:	
August 1980—No. 38 distribution of anionic charge	2,550.00
May 1980—No. 31 production of self-instructional programs for patient education	12,000.00
May 1980—No. 30 support of a full-researcher at Blard McIndoe Inst	10,000.00
May 1980—No. 24-A support for research techs utilized in nephrology lab on projects No. 17 and No. 24	20,000.00
April 1980—No. 29 research on urinary renin and B$_2$ microblobulin in renal transplant	2,500.00
January 1980:	
No. 26 (see No. 29)	1,500.00
Additional funding	2,000.00
January 1980:	
No. 25 research on ultrafiltration	10,000.00
No. 25-A additional funds	24,429.60
January 1980—No. 24 fund tech. salary in Neph. Res. Lab	17,000.00
January 1980—No. 23 fund research fellow	20,000.00
November 1979—No. 22 modulation of allogenic lumphocyte responses by tropho-blast membranes	10,000.00
October 1979—No. 20 systemic lupus erythematosus	2,000.00
July 1979—No. 10 support of hypertension study clinic at USC	2,540.00
May 1979—No. 7 contribution to Kidney House	300.00
February 1979—Purchase of multiple automated sample harvester for Dr. John McIntyre research	1,700.00
December 1978—Medical supplies to support renal research at MUSC	505.00
December 1978--Support of renal fellow at MUSC	14,500.00
September 1978:	
Audio-visual equipment for hypertension study clinic	343.14
Sponsorship of two VA members at SEDTA Mtg.	275.00
September 1978—Cost of two nurses for 4 months of hypertensive study clinic	6,400.00
June 1978:	
Purchase of fraction collector and varioperphex pump to aid research at MUSC	1,678.26
Purchase of 554 Silent Writer for research use at MUSC	2,007.67
1980-81—No. 60 rapid differentiation of salt sensitive and nonsalt sensitive hypertensive patients by Lasix Administration	14,000.00
September 1981—No. 78 travel for educational purposes	5,000.00
October 1981—No. 81 to maintain a fund for monthly research meetings of Neph. Div. of Dept. of Med. Furtherance of scientific and educational objectives	3,000.00
October 1981—No. 64A continuation of Project No. 64 for purchase of expendable laboratory supplies	5,000.00
February 1982—No. 85 study entitled "Autosomal Dominant Polycystic Kidney Disease: Presymptomatic Diagnosis in Children by Ultrasonography and Computered Tomography"	5,000.00
Chattanooga:	
May 1979—No. 6 sponsor Phil Walker to symposium on peritoneal dialysis	300.00
May 1979—30 control of hyperglycemia	35,000.00

September 1978—Sponsor two speakers at Nephrology Urology Update 1978	1,000.00
June 1978—Donation to Internal Medicine Foundation, Inc.	1,000.00
1980-81—No. 70 funding trip to Greece for attendance of Dr. Adel Shenouda at the 8th International Congress of Nephrology	1,807.00
1980-81—"Investigate the Association of Hyponatremia and schizophrenia"	24,890.60
December 1981—No. 82 funding for DCI annual staff party	1,000.00
March 1982—No. 86 support of a nephrology resident	18,500.00
Cincinnati:	
November 1979—No. 11 computerized medical information system (software package)	26,000.00
1980-81—No. 72 support of summer fellowship for study of "Myoglobin Nephrotoxicity: Modification by Verapamil"	2,000.00
1930-81—"Hemostatic Parameters in Renal Disease"	34,450.00
Columbia:	
June 1980—No. 33 support of a research technician for UMMC	14,368.00
July 1979—No. 13 fund research tech for UMMC	11,856.00
Lexington:	
October 1980—No. 47 renal research at UK	4,500.00
September 1980—No. 43 role of complement in transplant rejection, UKMC	15,000.00
August 1980—No. 41 purchase equipment for renal research at UKMC	23,000.00
June 1980—No. 32 research project on "Renal Hormones, Renal Function and Salt and Water Metabolism," Baehler	15,000.00
October 1980—No. 21 purchase of square wave electro-magnetic flow meter for VA hospital	3,300.00
July 1979—No. 14 support renal research at VA	3,000.00
July 1979—No. 12 support of fellow at UK	15,201.21
July 1979—No. 8 support of renal research technician	1,200.00
May 1979—No. 9 support of renal fellow at UK	10,781.25
September 1978—Contribution to UK Renal Division Research Fund.	14,000.00
June 1978—Support of Renal Fellow at UK for 1 year	15,200.00
1980-81—No. 75 "Familial Complement Deficiency and Glomerulonephritis," Wyatt/Baehler	10,000.00
1980-81—No. 62 hematological parameters in chronic hemodialysis patients after conversion to CAPD, Baehler	3,010.00
1980-81—No. 54 contrast media induced acute renal failure, Natarjan/Baehler	5,872.00
March 1981—No. 54-A support to fund technician's position	12,000.00
Nashville:	
October 1980—No. 32-A continuation of No. 32	4,245.00
September 1980—No. 42 integrated neurobehavioral function in clinical illnesses and treatments	35,948.20
August 1980—Additional funds for:	
16A	1,976.65
18A	7,906.60
19A	13,659.90
27B	22,771.00
August 1980—No. 37 support of VU nephrology division through fellowship salaries	43,257.50
July 1980—No. 39 withdrawal from the designated fund balance to reimburse 20 percent salary and fringe benefits for Ann Sanders	3,203.00
July 1980—No. 34 funding transplant program	82,000.00
May 1980—No. 32 hyperparathyroidism-adenoum vs. primary hyplasia vs. hypreplasis secondary to renal disease	13,215.78
April 1980—No. 28 summer research opportunity student stipend for summer 1980	1,750.00
February 1980:	
No. 27 core research support at VU	5,500.00
No. 27-A continuation of No. 27	17,153.00
No. 27-B continuation of No. 27	1,000.00
January 1980—No. 50 "Long Term Follow-up of Neurobehavioral Function in Dialysis and Transplant Patients"	1,000.00

October 1979—No. 19 study of "The Dialysis Disequilibrium Syndrome During Initial Hemodialysis in Patients with Acute or Chronic Renal Failure"	42,640.00
September 1979—No. 18 study of "Continuous Ambulatory Peritoneal Dialysis and Intermittent Peritoneal Dialysis"	15,038.00
August 1979—No. 16 study of "Dietary Maintenance of Chronic Uremic Patients"	9,733.00
August 1979—No. 15 funding salaries for the transplant program	66,094.00
June 1979—No. 5 publication of an educational handbook for prospective transplant patients	3,500.00
April 1979—No. 4 "Study 1: Proposed Clinical and Laboratory Study Protocols"	147,638.00
April 1979—No. 2 funding salaries for nursing personnel participating in NCDS program (Nat'l Cooperative Dialysis Study)	19,730.88
March 1979—No. 1 funding salaries of a research tech and two fellowship salaries	29,094.27
April 1978:	
Salary for treatment nurses	40,000.00
Fellow salary	11,461.50
Fellow salary	3,845.00
Fellow salary	7,500.00
Research tech	4,074.88
Rental cost for neurobehavioral testing site	342.56
Contribution to nurses' salaries for extra time and effort involved in carrying out NCDS	19.814.40
	89,038.34
May 1978—Additional cost of NCDS for direct patients care:	
Hiring four additional nurses	16,742.40
Extra compensation for present nurses	15.360.00
	32,102.40
1980-81—No. 77 continuation of No. 4, No. 16, No. 27, No. 27-A, No. 27-B, No. 32-A and No. 42	22,625.13
1980-81—No. 73 purchase of computer materials for the Division of Nephrology at VU for current and anticipated clinical research data mgt	2,310.00
1980-81—Donation to Vanderbilt Life Extension Fund (No. 71)	62,000.00
1980-81—Support of Nephrology Division at VU (No. 67) (pending)	95,872.00
1980-81—Continuation of No. 39, No. 42, No. 50, No. 63 (No. 63A)	1,550.00
1980-81—Multicenter Research Center (No. 65)	450,000.00
1980-81—No. 63 support of position for research technician	5,812.82
August 1981—No. 27-C continuation of No. 27	3,064.45
September 1981—No. 79 lease (possible purchase) of Pheresis machine	6,000.00
December 1981—No. 58A support of summer student stipend (cont. of No. 58)	2,500.00
January 1982—No. 84 consultation services in Department of Biomedical Engineering at VU	1,443.00
April 1982—No. 87 employment of research technician (pending)	12,533.80
April 1982—Development of medical information system (corporation-wide) for the care and treatment of patients (pending)	250,000.00
Tennessee clinics:	
December 1981—No. 83 transfer of $1 million to Third National Bank Corp. as agent with the entire amount and income if invested, to be used for the endowment of a Chair in Nephrology and toward further support and development of the Division of Nephrology in the VU School of Medicine (pending)	....

Dialysis Foundation of Southern Arizona, Inc.,
April 26, 1982.

Mr. John J. Salmon,
Chief Counsel, Committee on Ways and Means, House of Representatives, Longworth House Office Building, Washington, D.C.

SUBJECT: HEARING ON END-STAGE RENAL DISEASE PROGRAM REIMBURSEMENT—APRIL 22, 1982

Dear Mr. Salmon: My name is Andrew Guy, and I am the Executive Director of the Dialysis Foundation of Southern Arizona, a nonprofit provider of ESRD services, renal related research, and health science education. I am also the Chairman of the End-Stage Renal Disease Network VI. I am writing you in my capacity as Chief Executive Officer of the Foundation and request that this correspondence be added to the testimony presented to the Oversight Subcommittee that held a hearing on April 22, and that it be included in the proceedings of that hearing.

I urge the Subcommittee on Oversight to request that the Committee on Ways & Means ask Secretary Schweiker to place in abeyance the implementation of the proposed ESRD incentive dialysis rate (NPRM: February 12, 1982, Medicare Program: End-Stage Renal Disease Program Prospective Reimbursement for Dialysis Services).

It is my belief that statistical data that has been available to the Administrator (and her staff) of the Health Care Financing Administration and which, I believe, has been recently called to your attention, raises serious questions as to whether the proposed prospective reimbursement (incentive) rate that has been developed as required by Public Law 97-35 will meet its intended purpose or whether the rate now being considered will, in fact, become a barrier to achieving the goals of that legislation.

Self-dialysis:—The ESRD semiannual survey report for the second half of 1981 reflects a dramatic increase of 335 percent in the number of patients receiving continuous ambulatory peritoneal dialysis (CAPD) when compared to the report for the first half of 1980. This number is twice the number reported to the Subcommittee on Health of the Committee on Finance of the U.S. Senate by the Administrator of the Health Care Financing Administration in September. The increase in this type of home-self-dialysis has apparently occurred because of new technology and not because of any type of economically oriented payment mechanism.

It is imperative that the implications of this new treatment option, which was virtually unknown six years ago, be thoroughly considered before the incentive rate is implemented. The immediate and most obvious dangers present as a result of this very rapid increase in a relatively new technology are: the cost estimate included in the proposed incentive rate has been weighted heavily toward home hemodialysis and, therefore, does not take into account the cost of continuous ambulatory peritoneal dialysis (CAPD). If this trend in peritoneal dialysis continues, it may well become the dominant patient choice in the future and, thus, any payment mechanism must consider its implications.

The second danger in implementing the present incentive rate is related to the fact that the medical product manufacturer and supplier of continuous ambulatory peritoneal dialysis solutions holds a virtual monopoly on that product line at the present time. This company has significantly increased its prices dring the last 18 months. Until this situation is resolved, either by increasing projected costs for home self-care patients utilizing continuous ambulatory peritoneal dialysis or by the reestablishment of competitive market forces for these types of products with a possible reduction in these medical product costs, the implementation of the proposed incentive rate at its present published level would very possibly result in the establishment of a financial barrier to the greater use of home-CAPD therapy.

Mortality rate.—As of April 19, 1982, the national aggregate mortality rate for end-stage renal disease patients was 18 percent. The significance is not in the national average but rather the range from a low of 13.8 percent to a high of 24.5 percent.

The causes of this significant variation could be many, including patient age and acuity. A review of this data is important to determine what, if any, effect it will have on current program changes now being considered as well as estimates that have been provided for the future number of patients as well as program costs through the year 2000. It is a distinct possibility that when these increased mortality rates are taken into account, patient forecasts as well as future program costs will have to be reduced.

Incident rate.—The incident rate is the number of patients that are identified during a specific period of time as a ratio to the total population of an area.

The range in that incident rate is signficant, reflecting a low of 33.9 per million to a high of 143.7 per million. The existence of a fourfold difference must be investigated to identify the principal causes. The possibility that there has been a reinstitution of some type of subtle yet definite patient screening process in areas of the country cannot be ruled out. It must be remembered that the Medicare screen fee for dialysis has been held essentially intact since 1973 and when that is taken into account with the soaring inflationary costs during the last six years, the possibility that access to this type of care has been restricted because of cost pressures is a possibility. Clear identification must be obtained for the reasons of this range in the incident rate prior to any significant change in the payment mechanism.

Portion of ESRD patients covered by medicare program.—Testimony that has been provided by the administration indicates that approximately 93 percent of all patients suffering from irreversible kidney failure are covered under the Title 18 Program. Although this national statistic is correct, it does not reflect that there are portions of the country where a signficant minority of patients are not covered under the Medicare program. The current pending incentive rate and accompanying rules assume that all patients treated are under the program which is not accurate. Consideration must be given to those patients that are not Medicare beneficiaries, particularly in the identification of unique problems that might exist in these patient populations (American Indians as one example). If Medicare regulations are to cover both Medicare and non-Medicare patients, then review must be undertaken to insure that the rules are not punitive to these minority groups.

It is my personal belief that an incentive-type payment mechanism is both timely and appropriate for this type of medical care. I am concerned that the rate which has been recently published has serious flaws and is not reflective of the most recent experience in end-stage renal disease care. I have attached the statistical data that I have referred to which is from the semiannual survey reports that are mandated by HCFA to be collected through the ESRD Networks. It is to the ESRD Network's credit that they have maintained several task forces attempting to identify statistical data needed for this program and in the process, have collated this data and made it available to individual Networks and representatives of HCFA.

Cordially,

ANDREW D. GUY,
Executive Director.

Enclosures.

TOTAL CHRONIC DIALYSIS PATIENTS BY TREATMENT MODALITY

Thu Apr 8 1982
SOURCE: ESRD SEMI-ANNUAL SURVEY

NETWORK	SURVEY PERIOD	TOTAL PATIENTS	STAFF-ASSISTED		IN-UNIT SELF DIALYSIS		SELF-DIALYSIS TRAINING			HOME PATIENTS		
			HEMODIALYSIS	PERITONAL	HEMODIALYSIS	PERITONEAL	HEMODIALYSIS	PERITONEAL	CAPD	HEMODIALYSIS	PERITONEAL	CAPD
01	81/2	400	192	5	132	0	11	0	2	45	0	13
08	81/2	697	502	8	0	0	5	1	2	75	19	85
13	81/2	734	481	18	40	0	3	0	4	58	4	126
31	81/2	760	575	29	45	0	1	0	5	51	22	32
29	81/2	794	677	29	0	0	0	0	0	48	0	40
27	81/2	803	651	21	9	0	3	0	1	25	0	93
10	81/2	886	680	26	0	0	1	0	0	90	19	70
07	81/2	923	689	8	0	0	2	0	1	136	12	75
05	81/2	949	613	4	29	0	0	0	1	225	39	38
06	81/2	987	810	4	4	0	0	2	5	49	5	108
26	81/2	1149	862	20	35	0	24	1	4	130	30	43
17	81/2	1161	862	38	22	0	7	0	3	51	12	166
16	81/2	1217	649	11	0	0	16	0	7	319	0	215
23	81/2	1234	1062	5	22	0	1	0	0	53	8	83
12	81/2	1290	1152	8	13	0	4	5	0	48	15	45
21	81/2	1448	1051	3	0	0	10.	1	1	169	33	180
02	81/2	1460	798	34	4	0	16	0	5	432	28	143
09	81/2	1546	1144	6	0	0	16	0	6	199	13	162
30	81/2	1795	1413	24	16	0	7	1	2	141	54	137
14	81/2	2004	1438	90	25	0	13	0	8	158	24	248
28	81/2	2174	1847	20	12	0	5	2	0	186	12	90
32	81/2	2355	1823	72	73	0	32	5	2	169	27	152
22	81/2	2408	1857	152	21	0	5	0	4	125	39	205
03	81/2	2455	2003	1	80	0	18	0	5	160	5	183
24	81/2	2636	2173	22	34	7	11	7	5	130	45	202
20	81/2	2791	2356	30	37	3	6	0	3	139	19	198
15	81/2	2825	2459	73	76	0	22	0	2	90	9	94
18	81/2	3011	2380	4	7	0	18	0	4	329	50	219
19	81/2	3250	2946	20	6	0	3	0	8	72	15	180
11	81/2	4125	3416	37	82	0	15	0	15	200	65	295
25	81/2	4303	3641	80	27	0	30	0	24	305	5	151
04	81/2	4508	4035	8	66	0	47	1	4	93	14	240
		59078	47237	910	917	10	352	26	133	4500	642	4351
			48147		927		511			9493		

18.6% self care .

Thu Apr 8 1982
SOURCE: ESRD SEMI-ANNUAL SURVEY

TOTAL CHRONIC DIALYSIS PATIENTS BY TREATMENT MODALITY

	SURVEY	TOTAL	STAFF-ASSISTED		IN-UNIT SELF DIALYSIS		SELF-DIALYSIS TRAINING			HOME PATIENTS		
NETWORK	PERIOD	PATIENTS	HEMODIALYSIS	PERITONAL	HEMODIALYSIS	PERITONEAL	HEMODIALYSIS	PERITONEAL	CAPD	HEMODIALYSIS	PERITONEAL	CAPD
01	80/1	363	164	1	114	0	10	0	1	49	0	24
08	80/1	565	403	11	0	0	9	2	6	76	12	46
31	80/1	568	440	8	24	0	2	4	0	40	28	2
13	80/1	646	449	10	35	1	11	0	3	58	11	68
29	80/1	673	573	33	0	0	1	0	3	35	0	28
27	80/1	699	610	15	7	0	3	0	1	32	1	30
10	80/1	720	564	27	0	0	3	0	0	98	15	13
07	80/1	721	503	12	0	0	5	1	1	135	25	39
06	80/1	805	685	7	9	0	1	4	0	58	15	26
05	80/1	833	540	0	29	0	9	2	0	212	20	21
17	80/1	958	751	31	24	0	18	2	3	80	22	27
26	80/1	990	782	13	9	0	15	1	1	135	31	3
23	80/1	998	918	5	4	0	16	0	0	37	0	18
16	80/1	999	511	14	0	0	29	0	3	386	0	56
12	80/1	1089	990	1	7	0	6	4	0	61	8	12
21	80/1	1186	846	2	0	0	8	7	5	175	83	60
09	80/1	1264	944	3	0	0	16	0	1	226	21	53
02	80/1	1282	638	22	4	0	31	5	11	485	40	46
30	80/1	1519	1171	37	14	0	12	3	1	181	72	28
14	80/1	1748	1311	104	27	0	26	1	8	174	14	83
28	80/1	1900	1662	22	8	0	13	2	2	163	14	14
32	80/1	1975	1634	24	20	0	32	1	4	172	27	61
22	80/1	2040	1630	147	13	0	16	3	1	162	28	40
20	80/1	2123	1820	36	35	0	9	2	2	147	25	47
03	80/1	2179	1900	3	60	0	8	0	7	165	5	31
24	80/1	2306	1954	35	14	11	18	4	1	142	46	81
18	80/1	2440	1934	8	16	0	32	3	2	351	42	52
15	80/1	2518	2254	59	61	0	22	0	2	86	10	24
19	80/1	2599	2386	20	1	0	4	0	2	119	5	62
11	80/1	3397	2940	30	55	0	14	1	7	216	28	106
25	80/1	3756	3305	84	0	0	31	0	5	276	8	47
04	80/1	3931	3619	6	62	0	34	1	2	117	40	50
		49790	40851	830	652	12	464	53	85	4849	696	1298
			41681		664		602			6843		

TOTAL CHRONIC DIALYSIS PATIENTS BY TREATMENT MODALITY

Thu Apr 8 1982
SOURCE: ESRD SEMI-ANNUAL SURVEY

			STAFF-ASSISTED		IN-UNIT SELF DIALYSIS		SELF-DIALYSIS TRAINING			HOME PATIENTS		
NETWORK	SURVEY PERIOD	TOTAL PATIENTS	HEMODIALYSIS	PERITONAL	HEMODIALYSIS	PERITONEAL	HEMODIALYSIS	PERITONEAL	CAPD	HEMODIALYSIS	PERITONEAL	CAPD
01	80/2	376	183	0	118	0	9	0	0	46	0	20
08	80/2	604	439	7	0	0	7	0	2	71	13	65
31	80/2	643	511	21	24	0	4	1	2	43	22	15
13	80/2	675	458	12	33	1	7	1	2	54	16	91
29	80/2	710	604	33	0	0	1	0	1	38	3	30
27	80/2	727	611	19	12	0	2	0	4	33	0	46
07	80/2	750	541	11	0	0	0	0	1	131	21	45
10	80/2	788	612	25	0	0	1	0	0	97	19	34
06	80/2	871	726	7	7	0	0	0	4	59	7	61
05	80/2	885	531	2	28	0	5	6	2	230	46	35
17	80/2	968	749	33	31	0	6	0	3	69	8	69
26	80/2	1018	802	10	8	0	19	6	0	134	21	18
16	80/2	1046	553	12	0	0	25	1	3	350	0	102
23	80/2	1065	913	3	3	0	15	1	7	65	0	58
12	80/2	1158	1041	4	13	0	2	2	1	52	13	30
21	80/2	1277	909	2	0	0	11	0	1	179	55	120
09	80/2	1350	1009	2	0	0	15	0	2	218	15	89
02	80/2	1376	696	31	4	0	15	3	6	482	37	102
30	80/2	1605	1270	29	15	0	7	2	3	162	59	58
14	80/2	1834	1364	101	18	0	14	1	6	159	15	156
28	80/2	1954	1688	18	10	0	10	2	0	177	15	34
32	80/2	2074	1682	55	32	0	36	4	1	166	19	79
22	80/2	2181	1727	161	18	0	11	1	0	150	27	86
03	80/2	2257	1886	2	93	0	13	0	14	167	5	77
20	80/2	2288	1979	38	22	0	11	1	3	122	23	89
24	80/2	2434	2060	24	16	11	12	9	2	142	53	105
18	80/2	2594	2068	9	9	0	12	2	4	359	36	95
15	80/2	2631	2343	61	63	0	28	0	4	77	6	49
19	80/2	2815	2579	16	4	0	1	0	2	108	6	99
11	80/2	3640	3092	39	57	0	16	3	11	218	48	156
25	80/2	3920	3350	102	21	0	23	4	5	304	5	106
04	80/2	4094	3731	10	67	0	33	0	1	112	22	118
		52608	42707	899	726	12	371	50	97	4774	635	2337
		49740	43606		738		518					

17% some for of self care

Thu Apr 8 1982
SOURCE: ESRD SEMI-ANNUAL SURVEY

TOTAL CHRONIC DIALYSIS PATIENTS BY TREATMENT MODALITY

	SURVEY	TOTAL	STAFF-ASSISTED		IN-UNIT SELF DIALYSIS		SELF-DIALYSIS TRAINING			HOME PATIENTS		
NETWORK	PERIOD	PATIENTS	HEMODIALYSIS	PERITONAL	HEMODIALYSIS	PERITONEAL	HEMODIALYSIS	PERITONEAL	CAPD	HEMODIALYSIS	PERITONEAL	CAPD
01	81/1	370	186	0	118	0	6	0	0	42	0	18
08	81/1	633	455	8	0	0	9	1	5	72	14	69
31	81/1	711	539	26	41	0	8	1	2	48	22	24
13	81/1	742	494	19	37	2	2	0	5	62	4	117
29	81/1	742	617	25	11	0	0	0	8	48	0	33
27	81/1	759	620	21	13	0	3	0	21	22	0	59
07	81/1	835	599	8	0	0	1	0	1	139	18	69
10	81/1	841	641	23	0	0	4	0	1	92	24	56
05	81/1	922	546	2	51	0	5	6	2	229	46	35
06	81/1	958	794	8	6	0	2	0	10	50	4	84
17	81/1	1084	798	39	25	0	8	0	8	61	29	116
26	81/1	1092	840	10	14	0	27	2	0	139	31	29
16	81/1	1134	565	4	0	0	44	0	25	335	1	160
23	81/1	1140	989	5	9	0	3	0	0	57	0	77
12	81/1	1240	1102	11	12	0	3	0	0	48	19	45
02	81/1	1342	709	19	4	0	22	0	3	430	35	120
21	81/1	1385	978	1	0	0	8	1	1	179	43	174
09	81/1	1437	1074	3	0	0	14	0	8	210	12	116
30	81/1	1724	1358	17	17	0	14	4	5	155	49	105
14	81/1	1977	1293	98	168	0	20	3	10	157	25	203
28	81/1	2107	1790	20	15	0	5	1	5	193	12	66
32	81/1	2246	1762	48	39	0	72	4	9	165	28	119
22	81/1	2303	1801	158	21	0	6	2	4	141	27	143
03	81/1	2410	1888	1	181	0	10	0	8	164	8	150
24	81/1	2555	2131	32	25	8	10	5	5	130	41	168
20	81/1	2573	2187	31	36	0	6	0	5	129	27	152
15	81/1	2732	2405	65	74	0	17	0	6	91	5	69
18	81/1	2805	2223	4	8	0	19	3	4	339	35	170
19	81/1	2957	2693	22	2	1	3	0	9	84	17	126
11	81/1	3933	3275	41	53	0	23	2	43	195	59	242
25	81/1	4161	3502	104	17	0	40	3	7	323	5	160
04	81/1	4300	3884	10	60	0	43	1	10	100	17	175
		56150	44738	883	1057	11	457	39	230	4629	657	3449

Fri Apr 9 1982
SOURCE: ESRD SEMI-ANNUAL SURVEY

UNADJUSTED ANNUAL MORTALITY OF DIALYSIS PATIENTS
BASED ON SEMI-ANNUAL SURVEY

NETWORK	SURVEY PERIOD	PATIENTS RECEIVING CARE BEGINNING PERIOD			NEW PTS AT RISK (04A+04B/2)	POP. AT RISK (01+02+(1/2 NS))	TOTAL DEATHS (08A+08B)	MORTALITY RATE
		IN-UNIT	HOME	TOTAL				
	1980	539	404	943	168.00	1111.00	156	.14041
	1980	496	177	673	192.50	865.50	123	.14211
	1980	1837	402	2239	461.50	2700.50	394	.14589
	1980	479	77	556	116.50	672.50	101	.15018
	1980	900	262	1162	248.50	1410.50	215	.15242
	1980	1694	206	1900	420.00	2320.00	356	.15344
	1980	398	116	514	123.50	637.50	105	.16470
	1980	1648	170	1818	338.00	2156.00	356	.16512
	1980	2313	94	2407	441.50	2848.50	471	.16535
	1980	2818	310	3128	588.00	3716.00	640	.17222
	1980	529	235	764	169.00	933.00	161	.17256
	1980	890	48	938	185.00	1123.00	196	.17453
	1980	3199	283	3482	629.00	4111.00	725	.17635
	1980	898	84	982	208.50	1190.50	210	.17639
	1980	771	269	1040	252.00	1292.00	230	.17801
	1980	2245	161	2406	534.50	2940.50	531	.18058
	1980	635	547	1182	261.50	1443.50	261	.18081
	1980	284	69	353	55.50	408.50	74	.18115
	1980	1797	186	1983	412.00	2395.00	437	.18246
	1980	3537	160	3697	724.00	4421.00	812	.18366
	1980	624	46	670	134.50	804.50	153	.19018
	1980	775	168	943	207.50	1150.50	220	.19122
	1980	1141	270	1411	290.00	1701.00	329	.19341
	1980	1968	253	2221	538.50	2759.50	544	.19713
	1980	1382	219	1601	351.50	1952.50	393	.20128
	1980	1586	235	1821	422.50	2243.50	463	.20637
	1980	505	128	633	154.00	787.00	170	.21601
06	1980	650	79	729	196.50	925.50	201	.21717
	1980	555	52	607	146.50	753.50	165	.21897
	1980	1735	211	1946	429.50	2375.50	527	.22184
	1980	730	112	842	264.50	1106.50	269	.24310
	1980	588	121	709	204.00	913.00	242	.26506
		40146	6154	46300	9868.50	56168.50	10230	.18213

Fri Apr 9 1982
SOURCE: ESRD SEMI-ANNUAL SURVEY

UNADJUSTED ANNUAL MORTALITY OF DIALYSIS PATIENTS
BASED ON SEMI-ANNUAL SURVEY

NETWORK	SURVEY PERIOD	PATIENTS RECEIVING CARE BEGINNING PERIOD IN-UNIT	HOME	TOTAL	NEW PTS AT RISK (04A+04B/2)	POP. AT RISK (01+02+(1/2 NS))	TOTAL DEATHS (08A+08B)	MORTALITY RATE
	1981	568	198	766	250.00	1016.00	140	.13779
	1981	940	107	1047	228.50	1275.50	198	.15523
	1981	3507	415	3922	654.00	4576.00	753	.16455
	1981	585	462	1047	227.50	1274.50	210	.16477
	1981	2043	240	2283	464.50	2747.50	453	.16487
	1981	923	354	1277	254.00	1531.00	253	.16525
	1981	1717	227	1944	333.50	2277.50	382	.16772
	1981	717	552	1269	264.50	1533.50	260	.16954
	1981	3225	429	3654	688.00	4342.00	740	.17042
	1981	2151	298	2449	511.50	2960.50	513	.17328
	1981	1028	322	1350	291.00	1641.00	285	.17367
	1981	2485	144	2629	547.00	3176.00	552	.17380
	1981	310	66	376	59.50	435.50	77	.17680
	1981	1324	287	1611	303.50	1914.50	341	.17811
	1981	2596	212	2808	598.00	3406.00	611	.17938
	1981	2107	490	2597	521.50	3118.50	566	.18149
	1981	1994	263	2257	428.00	2685.00	493	.18361
	1981	537	85	622	147.50	769.50	142	.18453
	1981	1810	264	2074	458.50	2532.50	468	.18479
	1981	824	149	973	232.00	1205.00	226	.18755
	1981	621	271	892	158.00	1050.00	197	.18761
	1981	1502	331	1833	384.50	2217.50	422	.19030
	1981	648	79	727	139.00	866.00	165	.19053
	1981	857	174	1031	225.50	1256.50	240	.19100
	1981	3844	251	4095	790.50	4885.50	940	.19240
	1981	1063	95	1158	248.00	1406.00	273	.19416
	1981	454	149	603	143.50	746.50	145	.19423
	1981	516	164	680	154.50	834.50	164	.19652
06	1981	744	127	871	193.00	1064.00	213	.20018
	1981	1920	263	2183	487.00	2670.00	574	.21498
	1981	638	150	788	189.00	977.00	233	.23848
	1981	639	71	710	192.50	902.50	221	.24487
		44837	7689	52526	10767.50	63293.50	11450	.18090

THE FORUM OF END-STAGE RENAL DISEASE NETWORKS,
Los Angeles, Calif., April 27, 1982.

Mr. JOHN J. SALMON,
Chief Counsel, Committee on Ways and Means, Longworth House Office Building, Washington, D.C.

DEAR MR. SALMON: On behalf of the Forum of ESRD Networks, I am submitting five copies of this written statement for inclusion in the printed record of the House Ways and Means Subcommittee on Oversight's hearing of April 22, 1982 relative to: "The proposed regulations governing reimbursement under the Medicare ESRD Program." Although it is our understanding that the Subcommittee will hear testimony on network activities later this year, this statement specifically addresses the proposed regulations and the relationship of networks relative to their proper administration and evaluation.

The Health Care Financing Administration's (HCFA) proposal for implementing Congress' mandated dual composite rate structure will have an immediate impact on the majority of ESRD facilities in this country. How the providers of care will adjust to these new rates is not fully understood.

Congress has the responsibility for evaluating these changes and their impact on patient care.

Networks are the only mechanism currently in place which have the data and professional expertise necessary to assist Congress in assuring that renal patients are not adversely or unjustly penalized as a result of these Congressional and Administrative changes in the reimbursement policy. It is unfortunate that HCFA has recommended the elimination of networks at a time when their functions are absolutely critical to the continued health and safety of over 68,000 renal patients.

Members of Congress have been reviewing carefully the total ESRD program in order to determine the most effective mechanism for controlling costs without endangering the quality and appropriateness of care delivered to ESRD patients. While a consensus exists relative to the soundness of this objective, there is strong disagreement with respect to the most appropriate mechanism. Previous public laws and regulations aimed at encouraging less expensive treatment modalities have not been successful. The current proposal regulations have been met with criticism and fear by both providers and patients. The Forum believes that Congress is forced by HCFA to formulate legislation without the benefit of complete, accurate and timely ESRD data, the absence of which is referenced throughout the proposed regulations and emphasized by those who criticize them. The Forum asks that the Subcommittee give careful consideration to the critical need for accurate data, the historical inability of the national ESRD—Medical Information System (MIS) to provide such data, and the current role of networks in data-related activities.

The national ESRD-MIS, plagued with problems since the onset of the program, has been unable for nearly a decade to produce the data necessary for proper program management and administrative decision making. When networks were funded in 1978, they were told that the MIS would support their data needs relative to the performance of their required medical review functions. Recognizing that medical review without data is impossible, networks independently, and often in conflict with HCFA directives, developed their own manual patient data collection systems. It was, in fact, the access to data at the network level that led to identification of specific problems in the MIS. As a result, effective January 1, 1981, HCFA assigned to networks full responsibility for the collection, validation and submission of all non-reimbursement MIS forms. This was in addition to their responsibility for the Semi-Annual MIS Facility Survey and the MIS Patient Census. Just last year HCFA permitted networks to establish access to computerized data processing. Since that time the majority of networks have converted from manual to automated data systems.

The Forum regrets that HCFA has not made an effort to coordinate data activities between networks, nor have they requested our reports for your review. All activities now underway relative to providing a meaningful exchange and sharing of information between networks has been initiated by individual networks and coordinated via the Forum. The Forum itself was organized voluntarily by network chairpersons to meet this need for communication between networks.

In March, the Forum asked each network to send copies of the 1980 and 1981 MIS Semi-Annual Facility Survey forms to one network for compilation. Networks have been responsible for collecting and forwarding these forms to HCFA for the past three years. HCFA rarely publishes the data in a timely fashion and to our knowledge has not yet published any 1981 reports. Enclosed for your review are copies of the reports published by one network in less than a month. Please recognize that these data were produced primarily for network use, and thus several titles require clarification in order to be fully understood by a broader based audience. Also, network numbers have been omitted from some tables. I have sent you a copy of the packet especially developed for my local network area, and thus you will find "Network 4" identified and underlined on most of the tables. These tables are being sent to you because the Forum is impressed by the quality of the data and the timeliness in which they could be produced by a cooperative effort of 32 networks acting without HCFA assistance. Many of these tables, such as the ones on new patients per million population and mortality of dialysis patients, have never been produced by the HCFA's MIS.

In previous Congressional testimony, the Forum stated that if networks were continued in 1982 they would be able to provide data that characterize the dialysis and transplant patient population. Samples of such data are now available for your review and include socio-demographic characteristics, morbidity factors, and incidence, prevalence, and mortality rates. Unfortunately, the ESRD-MIS has not provided comparable data for the nation, even though networks have met their responsibility relative to the collection and submission of MIS forms.

Patients and providers have expressed their concerns relative to HCFA's plan for monitoring the impact of the proposed regulations on the quality of care rendered to patients. Serious questions have been raised as to what measures are planned to assure that appropriate care is provided in a fair and equitable manner.

Networks and their Medical Review Boards (MRBs) represent the only mechanism ready to respond to these concerns. Since 1978, MRBs nationwide have performed activities relative to their regulatory functions, which are summarized below: (See Section 405.2113, Federal Register, June 6, 1976):

"Monitoring and assessing the appropriateness of patients for the proposed treatment modalities;

"Evaluating the performance of facilities and physicians based on aggregate data for at least the following three areas: appropriateness of the proposed treatment modality; morbidity; and mortality;

"Performing medical care evaluation studies, which include the development of criteria and standards, data collection and display, interpretation of the findings, institution of corrective action, and reperformance of any study which indicates a problem;

"Performing in-depth studies as indicated;

"Offering recommendations for improvements and reporting inappropriate or substandard care to the Secretary".

Medical Review Boards have met their responsibilities relative to these functions. The majority of networks have conducted studies on the appropriate selection of patients for home dialysis, and can update these studies as necessary. Criteria sets and the results of these studies are available for your review at any time. The range of topics selected by networks for in-depth study is impressive. The enclosed booklet developed by the Forum provides a listing of these studies and other related activities performed by networks during 1981.

HCFA has stated that "continuous ambulatory peritoneal dialysis (CAPD) is the preferred treatment for many patients." Currently, there is no medical evidence to support this position as long-term clinical experience is just beginning. In addition, data are not available to support a conclusion that CAPD is a less costly treatment option. Although networks do not collect actual cost data, they are conducting studies which will help determine how this treatment modality compares to other forms of dialysis in medical effectiveness and cost by taking into account the rate and duration of hospitalization. This is but one example of how networks simultaneously evaluate the effectiveness of care and associated costs.

HCFA is required to report annually to Congress on the total ESRD program, including the role of networks. In order to prepare this report, HCFA requires networks to submit an annual report documenting all activities. Unfortunately, network achievements have, for the most part, been omitted from HCFA's report to Congress.

Members of the Forum have had the opportunity to review the draft copy of HCFA's 1980 ESRD Report to Congress and compare it to the final document. During the revision process, HCFA omitted key sentences including the following on the role of networks relative to data:

"The efforts (networks role in collecting and submitting MIS forms) culminated in 100 percent compliance in Facility Survey forms, resulting in increased validity and accuracy of the ESRD patient data base."

"The data (collected by networks for their individual patient data systems) supplement the national MIS data, making possible profile analysis on an individual network basis in areas such as incidence, prevalence and survival rates by treatment modality, age/sex distribution of patients, primary diagnosis statistics, and facility capacity reports."

Because the Forum believes that Congress is not receiving from HCFA an adequate or honest summary of network achievements, we prepared the enclosed booklet, which highlights network activities in 1981. We feel confident that you will be impressed by its content, and as puzzled as we are when you compare it to reports from HCFA.

Recently, Dr. Carolyne Davis, Administrator of HCFA, was asked to testify on the ESRD Program before a Subcommittee of the House Government Operations Committee. When asked how HCFA monitored the quality of care, she responded that this was the function of networks. She was then asked if HCFA had recommended the elimination of networks, and she responded yes. When asked why HCFA recommended the elimination of networks, she stated because (1) the networks had not shown that they were successful enough to warrant their cost, and (2) the networks' planning role is hampered by the individuals' conflicts of interest. These reasons clearly demonstrate HCFA's lack of understanding of the network program. First, the total network budget for 1982 was $4.5 million, or less than .3 percent of the estimated $1.8 billion total annual ESRD program budget. Considering network achievements relative to data collection, validation and application for assuring the quality of patient care, it seems unreasonable to recommend the elimination of networks for reasons of cost. Secondly, networks have never had any authority relative to the planning process. Networks provide information, such as incidence and prevalence data, to those local and regional agencies legally responsible for health planning. The Forum believes Dr. Davis has misled Congress as to the functions and cost-effectiveness of the network program.

In conclusion, networks comprise a relatively inexpensive, functioning system that has already demonstrated the ability to generate meaningful data impacting on the quality of care, cost control, and the effective administration of the total program. No other system exists for carrying out these functions and the interruption of network activities would prove disastrous to the management of the ESRD program.

The Forum urges your thoughtful consideration of this statement as you review comments submitted by those who are concerned as to the impact of the proposed regulations on the patients with end-stage renal disease. We are optimistic that you will recommend denial of HCFA's proposal to eliminate networks.

If you have any questions or wish to review documents cited in this statement, please feel free to contact me.

Sincerely,

DOMINICK E. GENTILE, M.D.,
Chairman, Forum of ESRD Networks.

Enclosures.

THE FORUM
OF END-STAGE RENAL DISEASE NETWORKS
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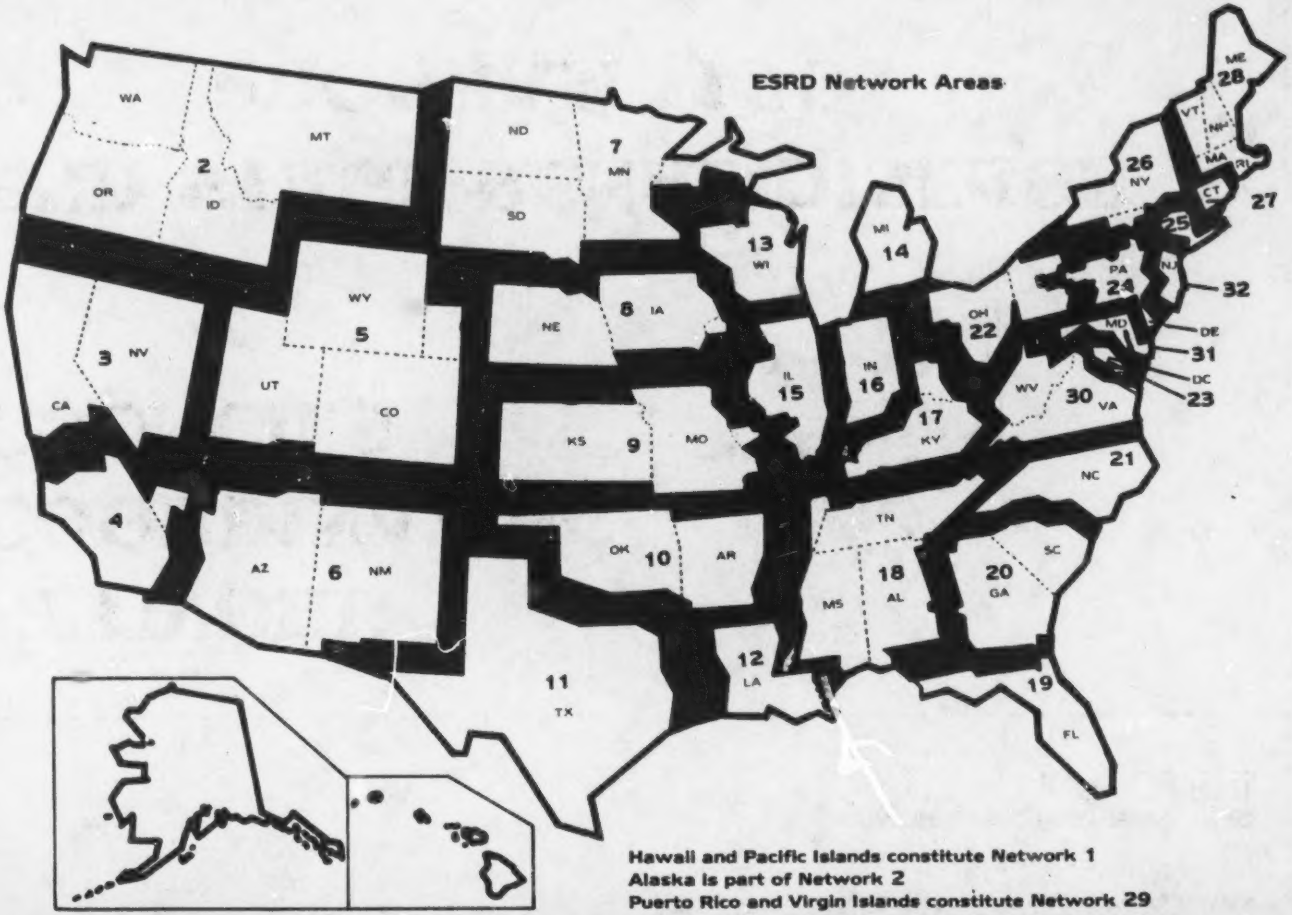
NETWORK COORDINATING COUNCILS

END STAGE RENAL DISEASE PROGRAM 1981

ESRD Network Areas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Hawaii and Pacific Islands constitute Network 1
Alaska is part of Network 2
Puerto Rico and Virgin Islands constitute Network 29

The Forum of Network Coordinating Councils is a national voluntary organization created to facilitate the exchange of information and ideas among the End Stage Renal Disease Networks. The Forum seeks a concensus of opinion from Networks on common national matters and expresses those concerns to the appropriate governmental agencies and congressional representatives.

We have prepared this booklet which we feel highlights the purpose, responsibilities, and accomplishments of the Network Coordinating Councils.

Respectfully,

D. E. Gentile, M.D.

Dominick E. Gentile, M.D.
Chairman

Introduction

Legislative History. The End Stage Renal Disease (ESRD) Program was established nationally as a result of the passage of amendments to the Social Security Act in 1972. This legislation provided, on July 1, 1973, federal responsibility for financing the care for nearly all persons with ESRD, and for the reimbursement of most of the costs for kidney dialysis and transplantation. The authority, given under P.L. 92-603, Section 2991 essentially states that individuals with chronic kidney failure are eligible for Medicare. Reimbursement under Medicare was authorized for kidney transplant and dialysis to facilities which meet specific certification requirements.

On June 23, 1978, Titles II and XVIII of the Social Security Act were amended through P.L. 95-292 to make improvements in the ESRD Program. The new laws removed many "disincentives" for home dialysis and transplantation. The bill was designed to correct a number of inequities, improve the quality of care, and provide incentives for modalities of treatment which may increase the potential for rehabilitation and improve cost effectiveness for the ESRD Program. The Health Care Financing Administration (HCFA) is assigned the primary responsibility for overseeing the medical, fiscal, and related aspects of the ESRD Program. The following are the objectives of the ESRD Program:

A. To assist beneficiaries who have been diagnosed as having End Stage Renal Disease (ESRD) to receive the care they need;

B. To encourage proper distribution and effective utilization of ESRD treatment resources while maintaining or improving the quality of care; and

C. To provide the flexibility necessary for the efficient delivery of appropriate care by physicians and facilities.

Network Functions. The Social Security Act (Section 1881 (c)), also specifies three primary purposes for ESRD Networks which are:

A. To assure effective and efficient administration of benefits for patients with ESRD.

B. To coordinate planning and quality assurance activities and exchange of data with relevant local State and Federal agencies.

C. To encourage use of treatment settings most compatible with the successful rehabilitation of patients.

Medicare Trust Funds started funding Networks in the autumn of 1977. Thirty-two Networks are operational in each of the 50 states and U.S. territories. Networks are comprised of representatives from every Medicare-certified renal care facility. The diversified membership includes nephrologists, transplant surgeons, renal patients, nurses, dietitians, social workers, technicians, administrators, consumers, and adjunct representatives from affiliated organizations involved in the ESRD Program.

Networks are continually developing and refining the systems of medical peer review for ESRD care. Network Medical Review Boards develop criteria and standards, identify problems, and develop plans of corrective action, to improve clinical practice. Continual monitoring, follow-up, and reevaluation have been established. Networks promote home dialysis and renal transplantation by setting local goals and implementing policy to encourage these modalities. Networks provide an effective bridge between the federal government, the ESRD providers, and the consumers of these specialized services. Networks are resources for the federal government, congressional policy makers, and state and local agencies. Also, Networks provide timely data and statistics to agencies and providers of care.

QUALITY ASSURANCE AND SPECIAL INITIATIVES

The primary responsibility and function of the Networks is to ensure that quality of care is maintained in the ESRD dialysis and transplant facilities within their geographic boundaries. The audits, medical care evaluation studies, data analyses, facility site visits, and investigative studies that were conducted or initiated during 1981 demonstrate that an effective peer evaluation and monitoring process is being implemented. Highlights of this year's accomplishments in this area are:

- Completion of appropriate morbidity and mortality studies:
    - studies of the frequency of hospitalization;
    - analyses of patient profiles by modality of treatment, facility utilization, demographic characteristics, primary disease, and survival.
- Initiation of studies on the clinical management of renal osteodystrophy, treatment of anemia, control of potassium, blood pressure control, peritonitis in the peritoneal dialysis population, improvement of fistula access in hemodialysis patients, control of bacteremia and other infections.
- Conduction of CAPD studies covering morbidity, mortality, and rehabilitation status.

Patient Care:

- preparation of criteria sets and assessment methods for patient nutritional status.
- development of criteria for initiation of dialysis treatment.
- development of guidelines for identification, prevention, management, and surveillance of hepatitis B and non-A, non-B hepatitis.
- preparation of guidelines for water treatment safety.
- joint investigations with PSROs, State Health Departments, and Medical Regional offices on the quality of care in ESRD facilities.
- development of standardized forms for interfacility transfer of patient information, including nursing Kardex forms and long term patient care forms.
- studies on the safety of dialysis equipment.
- preparation of guidelines for training new dialysis staff, including the development of staff role definitions.
- development and use of questionnaires to determine patient knowledge and/or satisfaction with treatment modality.
- development and conduction of studies of team site visits.

Special Initiatives:

- Reasons for nursing shortages in ESRD facilities.
- Initiation of patient time and travel distance studies.
- Evaluation of the protocol for ESRD pediatric services.
- Conduction of studies of the salary ranges for nurses and technicians.
- Arrangement of group rates for routine lab work in order to reduce costs and waiting time for lab results.
- Proposal of the revisions of local health codes which affect ESRD facilities.
- Development of uniform ESRD definitions for levels and types of care provided for acute and chronic patients to assist Medicare carriers in evaluating professional fee reimbursement of physicians.

HOME DIALYSIS AND TRANSPLANTATION

Networks have placed a major emphasis on encouraging home dialysis or transplantation for those patients who are medically and psychologically suited for these modalities of treatment. The approaches and methods utilized by the Networks are diverse. The following highlights reflect the Networks'extensive involvement in this complex area:

- Development of criteria to identify and evaluate candidates for home dialysis or transplantation.
- Analysis of data on morbidity and mortality associated with home dialysis or transplantation.
- Establishment of training programs and the development of standardized long-term patient care plans.
- Development of educational activities and materials for patients and facility staff such as seminars, workshops, booklets, and posters.
- Analysis of patient profile characteristics by modality of treatment.
- Working with other agencies to heighten hospital and public awareness of the need to increase organ procurement.

EDUCATION

Networks have devised programs of education for their patient populations, staff, and the general public. Among the approaches and media that have been developed are:

- Professional education:
  - educational seminars and workshops (sometimes held in conjuction with state and local health agencies) in the following areas: dialysis, transplantation, hepatitis control, nutrition, quality of care, organ donation and retrieval, rehabilitation, medical records, form use, budget reduction, ethical issues, stress management, and training for new staff members.
- Patient education:
  - information on the treatment modalities available, conduct of dietary workshops and development of nutritional booklets, preparation of patient information booklets.
- Public education:
  - organ donor programs through the use of brochures and posters, organization of speakers bureaus for talks to citizen groups, newsletter publications for patients and staff for distribution to health agencies, operation of telephone resource lines, and development and operation of libraries containing materials on ESRD.

PATIENT ACTIVITY

Consumer Advisory Groups have been established in two-thirds of the Networks. These groups serve as a source of support and information for ESRD patients. Among the activities of these groups are:

- Input into developing literature for patient education, including publications on patient's rights, grievance procedures, nutritional handbooks, and booklets on the various modes of treatment.
- Planning and implementation of patient conferences for educational purposes.
- Participation in Medical Review studies.
- Joint action with other groups or agencies such as NAPHT, the Kidney Foundation, Renal Dietitians, and State Legislators.

REHABILITATION

In 1981, 50% of the Networks recognized that the investigation of the problems associated with rehabilitation was of major importance. The variety of studies and educational efforts that have been completed or initiated are briefly described below:

- One-fourth of the Networks have studies in process which are designed to identify factors in the patient population that present barriers to the return to employment. Among the factors being studied were the levels of activity or employment status prior to the initiation of ESRD treatment.

- Conferences and workshops were conducted by Networks for ESRD staff to ptomote the rehabilitation of patients.

- Joint meetings were held with state rehabilitation agencies to explore and assist in clarifying the problems associated with encouraging rehabilitation among ESRD patients.

- Establishment of Rehabilitation Task Forces to investigate barriers to rehabilitation.

HEALTH PLANNING

Networks prepare information for joint use with local and regional agencies involved in ESRD health planning. Examples are:

- Preparation of data for use in determining the need for expansion or for new ESRD applications.
- Development of review criteria for the need for ESRD services.
- Development of incidence and prevalence data for long and short term ESRD planning (growth predictions and utilization patterns are determined).
- Promotion of the efficient use of existing services.
- Assistance in updating state health plans to ensure the delivery of quality care to ESRD patients.

DATA ACTIVITY

Networks have established either manual or computerized data systems for use in reporting ESRD activity to MIS. Two-thirds of the Networks have established computerized data systems. Activities and projects carried out by the Networks in the area of data management include:

- Establishment of a baseline patient-specific data system in some Networks (which is more detailed in those Networks with computerized data programs).
- Collection and validation of patient specific data reported on MIS non-reimbursement forms and the MIS 6-month facility survey forms.
- Use of data to assist in ESRD application review process by local and state health planning agencies. These agencies use Network data as a basis for the utilization review and certificate of need process. The data reflect current utilization and resource availability.
- Development of profile analysis of patient populations.
- Collection of data used for long term planning of ESRD health services.
- Assistance to other agencies (GAO, CDC, NIH) in their studies of the ESRD problem.
- Provision of feedback to Network facilities on the status of their populations. Quarterly and annual reports which reflect activity and type of treatments are produced.

ESRD Statistics

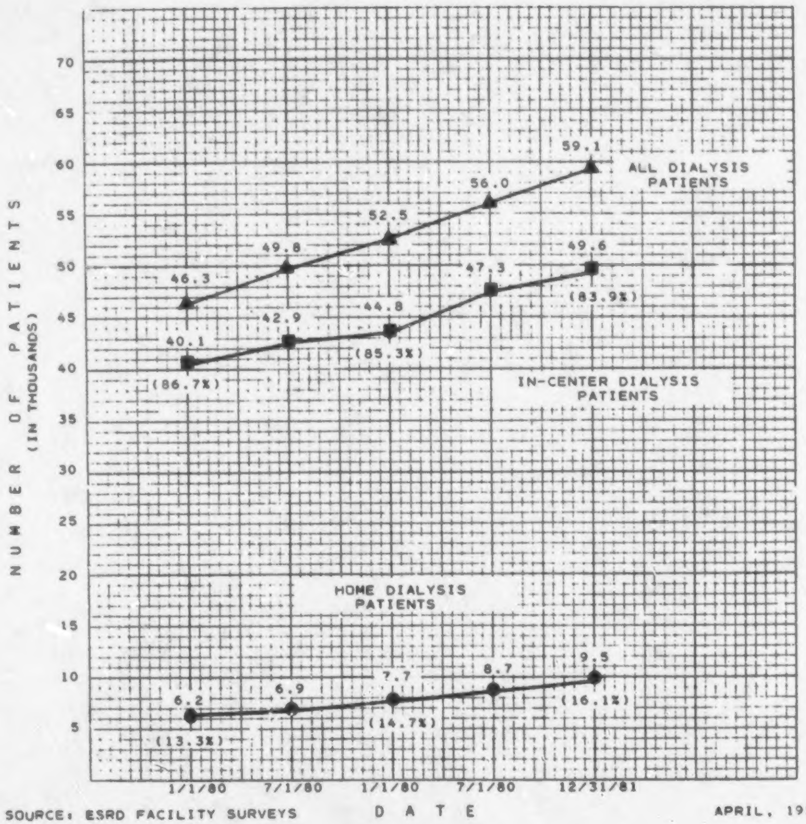
Data Overview. Networks are a local source of data and statistics on the ESRD patient population. Networks are able to provide current information to their own facilities, local organizations, and government agencies. Coordination and sharing of data between Networks for comparative analysis and the development of a national overview has recently been initiated. The following material is a product of inter-Network cooperation and highlights recent activities in the various modalities of treatment.

RATIO OF PATIENTS TRAINED FOR HOME DIALYSIS AND DIALYSIS PATIENTS
TRANSPLANTED TO AVERAGE NUMBER OF DIALYSIS PATIENTS PER SURVEY PERIOD
JANUARY, 1980 -- DECEMBER, 1981

	SURVEY PERIOD			
	Jan.-June, 1980	July-Dec., 1980	Jan.-June, 1981	July-Dec., 1981
Average Number of Dialysis Patients During Survey Period	51,366	54,586	57,825	61,266
Patients Completing Home Training	2,032	2,416	2,688	2,591
Ratio of Home Trained Patients To Average Number of Dialysis Patients	.0396	.0443	.0465	.0423
Dialysis Patients Receiving a Transplant	1,985	2,091	2,093	2,189
Ratio of Dialysis Patients Receiving a Transplant to Average Number of Dialysis Patients	.0386	.0383	.0362	.0357

SOURCE: ESRD Facility Survey
April, 1982

NUMBER (IN THOUSANDS) OF CHRONIC DIALYSIS PATIENTS BEING TREATED BY MEDICARE CERTIFIED SUPPLIERS OF ESRD SERVICES IN THE UNITED STATES BY TREATMENT SETTING JANUARY, 1980 - DECEMBER, 1981



SOURCE: ESRD FACILITY SURVEYS

APRIL, 1982

The total number of ESRD patients receiving dialysis continues to grow. The proportion of patients being treated at home is slowly increasing, due in part, to the development of Continuous Ambulatory Peritoneal Dialysis (CAPD). Sufficient long term experience with this treatment modality does not yet exist. Therefore, it is impossible to know what the effect CAPD will have on the resources of the program.

RATIO OF PATIENTS TRAINED FOR HOME DIALYSIS AND DIALYSIS PATIENTS TRANSPLANTED TO NUMBER OF PATIENTS STARTING DIALYSIS FOR THE FIRST TIME
JANUARY, 1980 -- DECEMBER, 1981

	SURVEY PERIOD			
	Jan.-June, 1980	July-Dec., 1980	Jan.-June, 1981	July-Dec., 1981
Patients Starting Dialysis For First Time	10,133	9,604	10,958	10,577
Patients Completing Home Dialysis Training:	2,032	2,416	2,688	2,591
Home Trained To New Start Ratio:	.201	.252	.245	.245
Dialysis Patients Transplanted:	1,985	2,091	2,093	2,189
Transplanted To New Start Ratio:	.196	.218	.191	.207

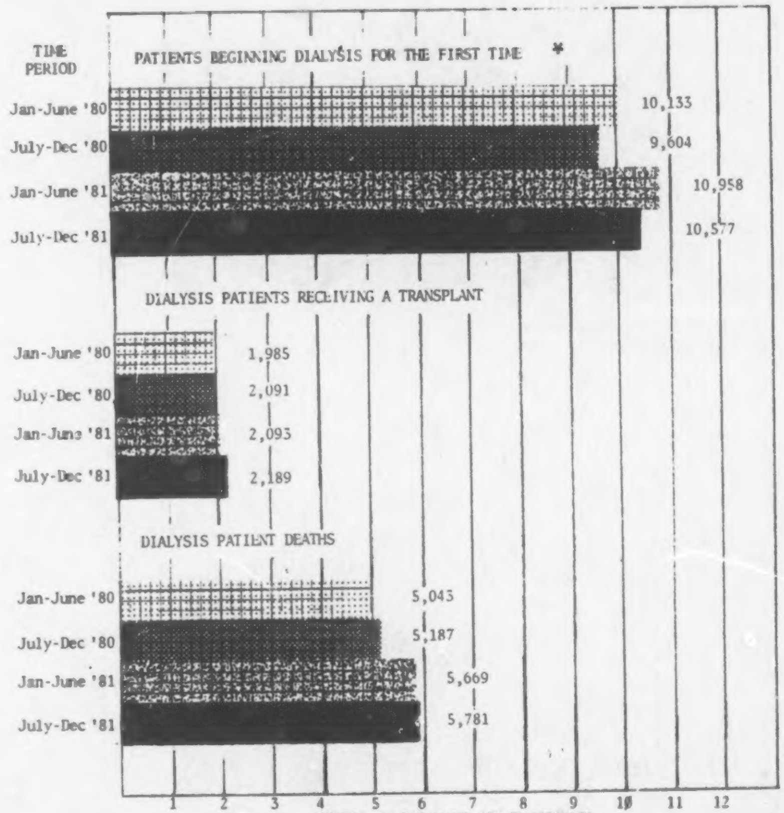
Reported Medicare Eligibility Status of Chronic Dialysis Patients Being Treated By Medicare Certified ESRD Facilities in the United States From June, 1980 to December, 1981

	DATE							
	JUNE, 1980		DECEMBER, 1980		JUNE, 1981		DECEMBER, 1981	
ELIGIBILITY STATUS	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Medicare Eligible	42,374	85.1	44,991	85.5	48,843	87.0	51,512	87.2
Pending Medicare	3,872	7.8	3,854	7.3	3,596	6.4	3,765	6.4
Non-Medicare	3,527	7.1	3,763	7.2	3,698	6.6	3,796	6.4
Unknown	17	---	0	---	13	---	5	---
TOTAL PATIENTS	49,790	100.0	52,608	100.0	56,150	100.0	59,078	100.0

SOURCE: ESRD Facility Surveys

April, 1982

MAJOR REASONS FOR CHANGES IN THE
NUMBER OF CHRONIC DIALYSIS PATIENTS
TREATED BY MEDICARE CERTIFIED SUPPLIERS
OF ESRD SERVICES IN THE UNITED STATES
JANUARY, 1980 -- DECEMBER 31, 1981



SOURCE: ESRD FACILITY SURVEY

APRIL, 1982

The ratio of patients receiving a transplant compared with the average number of dialysis patients has slowly decreased during the past four 6-month periods. The proportion of dialysis patients that expired during these same time periods has remained relatively constant. However, the number of new patients entering treatment for the first time has increased by 9% between 1980 and 1981.

* Aggregate Data: Double counting may exist

Addresses of ESRD Network Coordinating Councils

NETWORK #: 1. 1427 Dillingham Boulevard, Suite 201
Honolulu, Hawaii 96817
2. 157 Yesler Way, Suite 409
Seattle, Washington 98104
3. 2247 Union Street
San Francisco, California 94123
4. 6399 Wilshire Boulevard, Suite 402
Los Angeles, California 90048
5. 1390 Logan Street, Suite 206
Denver, Colorado 80203
6. Surge Building, Room 215, Frontier N.E.
Albuquerque, New Mexico 87106
7. 2829 University Avenue, S.E., Suite 544
Minneapolis, Minnesota 55414
8. 8611 Hickman Road
Des Moines, Iowa 50322
9. 20 West 9th Street, Suite 605
Kansas City, Missouri 64105
10. 1117 North Shartel, Suite 400, Hexagon Center
Oklahoma City, Oklahoma 73103
11. 1616 Gateway Boulevard, Suite 102
Richardson, Texas 75080
12. 5420 Corporate Boulevard, Suite 301
Baton Rouge, Louisiana 70808
13. 2825 North Mayfair Road
Milwaukee, Wisconsin 53222
14. 2000 Hogback Road, Suite 6
Ann Arbor, Michigan 48104
15. 828 South Second Street
Springfield, Illinois 62704
16. 911 East 86th Street, Room 202
Indianapolis, Indiana 46240

NETWORK #: 17. Post Office Box 4098
Lexington, Kentucky 40544
18. 131-A Sanders Ferry Road
Hendersonville, Tennessee 37075
19. 1 Davis Boulevard, Suite 304
Tampa, Florida 33606
20. 148 International Boulevard, Suite 550
Atlanta, Georgia 30303
21. Post Office Box 18347, 3900 Merton Drive, Suite 151
Raleigh, North Carolina 27619
22. Administration Center, Keystone Building
3520 Fifth Avenue, Suite 300
Pittsburgh, Pennsylvania 15213
23. 4701 Willard Avenue, Suite 610
Chevy Chase, Maryland 20015
24. 1003 West 9th Avenue, Suite H
King of Prussia, Pennsylvania 19406
25. 2 East 103rd Street
New York, New York 10029
26. 990 Seventh North Street
Liverpool, New York 13088
27. 396 Orange Street
New Haven, Connecticut 06511
28. 120 Boylston Street, Room 303
Boston, Massachusetts 02116
29. Metropolitan Shopping Center, Reparto Metropolitano
San Juan, Puerto Rico 00935
30. 700 Building, Suire 1422, 700 East Main Street
Richmond, Virginia 23219
31. 1204 Maryland Avenue
Baltimore, Maryland 21201
32. The Jefferson Building, 330 Milltown Road
East Brunswick, New Jersey 08816

Selected Profiles of Medicare
Certified Suppliers of ESRD Services
in the United States by Network

January 1, 1980 - December 31, 1981

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Thu Apr 8 1982
SOURCE: ESRD SEMI-ANNUAL SURVEY

TOTAL CHRONIC DIALYSIS PATIENTS BY TREATMENT MODALITY

	SURVEY	TOTAL	STAFF-ASSISTED		IN-UNIT SELF DIALYSIS		SELF-DIALYSIS TRAINING			HOME PATIENTS		
NETWORK	PERIOD	PATIENTS	HEMODIALYSIS	PERITONAL	HEMODIALYSIS	PERITONEAL	HEMODIALYSIS	PERITONEAL	CAPD	HEMODIALYSIS	PERITONEAL	CAPD
01	80/1	363	164	1	114	0	10	0	1	49	0	24
08	80/1	565	403	11	0	0	9	2	6	76	12	46
31	80/1	568	460	8	24	0	2	4	0	40	28	2
13	80/1	646	449	10	35	1	11	0	3	58	11	68
29	80/1	673	573	33	0	0	1	0	3	35	0	28
27	80/1	699	610	15	7	0	3	0	1	32	1	30
10	80/1	720	564	27	0	0	3	0	0	98	15	13
07	80/1	721	503	12	0	0	5	1	1	135	25	39
06	80/1	805	685	7	9	0	1	4	0	58	15	26
05	80/1	833	540	0	29	0	9	2	0	212	20	21
17	80/1	958	751	31	24	0	18	2	3	80	22	27
26	80/1	990	782	13	9	0	15	1	1	135	31	3
23	80/1	998	918	5	4	0	16	0	0	37	0	18
16	80/1	999	511	14	0	0	29	0	3	386	0	56
12	80/1	1069	990	1	7	0	6	4	0	61	8	12
21	80/1	1186	846	2	0	0	8	7	5	175	83	60
09	80/1	1264	944	3	0	0	16	0	1	226	21	53
02	80/1	1282	638	22	4	0	31	5	11	485	40	46
30	80/1	1519	1171	37	14	0	12	3	1	181	72	28
14	80/1	1748	1311	104	27	0	26	1	8	174	14	83
28	80/1	1900	1662	22	8	0	13	2	2	163	14	14
32	80/1	1975	1634	24	20	0	32	1	4	172	27	61
22	80/1	2040	1630	147	13	0	16	3	1	162	28	40
20	80/1	2123	1820	36	35	0	9	2	2	147	25	47
03	80/1	2179	1900	3	60	0	8	0	7	165	5	31
24	80/1	2306	1954	35	14	11	18	4	1	142	46	81
18	80/1	2440	1934	8	16	0	32	3	2	351	42	52
15	80/1	2518	2254	59	61	0	22	0	2	86	10	24
19	80/1	2599	2386	20	1	0	4	0	2	119	5	62
11	80/1	3397	2940	30	55	0	14	1	7	216	28	106
25	80/1	3756	3305	84	0	0	31	0	5	276	8	47
04	80/1	3931	3619	6	62	0	34	1	2	117	40	50
		49750	40851	830	652	12	464	53	85	4849	696	1298

TOTAL CHRONIC DIALYSIS PATIENTS BY TREATMENT MODALITY

Thu Apr 8 1982
SOURCE: ESRD SEMI-ANNUAL SURVEY

	SURVEY	TOTAL	STAFF-ASSISTED		IN-UNIT SELF DIALYSIS		SELF-DIALYSIS TRAINING			HOME PATIENTS		
NETWORK	PERIOD	PATIENTS	HEMODIALYSIS	PERITONAL	HEMODIALYSIS	PERITONEAL	HEMODIALYSIS	PERITONEAL	CAPD	HEMODIALYSIS	PERITONEAL	CAPD
01	80/2	376	183	0	118	0	9	0	0	46	0	20
08	80/2	604	439	7	0	0	7	0	2	71	13	65
31	80/2	643	511	21	24	0	4	1	2	43	22	15
13	80/2	675	458	12	33	1	7	1	2	54	16	91
29	80/2	710	604	33	0	0	1	0	1	38	3	30
27	80/2	727	611	19	12	0	2	0	4	33	0	46
07	80/2	750	541	11	0	0	0	0	1	131	21	45
10	80/2	788	612	25	0	0	1	0	0	97	19	34
06	80/2	871	726	7	7	0	0	0	4	59	7	61
05	80/2	885	531	2	28	0	5	6	2	230	46	35
17	60/2	968	749	33	31	0	6	0	3	69	8	69
26	80/2	1018	802	10	8	0	19	6	0	134	21	18
16	80/2	1046	553	12	0	0	29	1	3	350	0	102
23	80/2	1065	913	3	3	0	15	1	7	65	0	58
12	80/2	1158	1041	4	13	0	2	2	1	52	13	30
21	80/2	1277	909	2	0	0	11	0	1	179	55	120
09	80/2	1350	1009	2	0	0	15	0	2	218	15	89
02	80/2	1376	696	31	4	0	15	3	6	482	37	102
30	80/2	1605	1270	29	15	0	7	2	3	162	59	58
14	80/2	1834	1364	101	18	0	14	1	6	159	15	156
28	80/2	1954	1688	18	10	0	10	2	0	177	15	34
32	80/2	2074	1682	55	32	0	36	4	1	166	19	79
22	80/2	2181	1727	161	18	0	11	1	0	150	27	86
03	80/2	2257	1886	2	93	0	13	0	14	167	5	77
20	80/2	2288	1979	38	22	0	11	1	3	122	23	89
24	80/2	2434	2060	24	16	11	12	9	2	142	53	105
18	80/2	2594	2068	9	9	0	12	2	4	359	36	95
15	80/2	2631	2343	61	63	0	28	0	4	77	6	49
19	80/2	2815	2579	16	4	0	1	0	2	108	6	99
11	80/2	3640	3092	39	57	0	16	3	11	218	48	156
25	80/2	3920	3350	102	21	0	23	4	5	304	5	106
04	80/2	4094	3731	10	67	0	33	0	1	112	22	118
		52608	42707	899	726	12	371	50	97	4774	635	2337

TOTAL CHRONIC DIALYSIS PATIENTS BY TREATMENT MODALITY

Thu Apr 8 1982
SOURCE: ESRD SEMI-ANNUAL SURVEY

	SURVEY	TOTAL	STAFF-ASSISTED		IN-UNIT SELF DIALYSIS		SELF-DIALYSIS TRAINING			HOME PATIENTS		
NETWORK	PERIOD	PATIENTS	HEMODIALYSIS	PERITONAL	HEMODIALYSIS	PERITONEAL	HEMODIALYSIS	PERITONEAL	CAPD	HEMODIALYSIS	PERITONEAL	CAPD
01	81/1	370	186	0	118	0	6	0	0	42	0	18
08	81/1	633	455	8	0	0	9	1	5	72	14	69
31	81/1	711	539	26	41	0	8	1	2	48	22	24
13	81/1	742	494	19	37	2	2	0	5	62	4	117
29	81/1	742	617	25	11	0	0	0	8	48	0	33
27	81/1	759	620	21	13	0	3	0	21	22	0	59
07	81/1	835	599	8	0	0	1	0	1	139	18	69
10	81/1	841	641	23	0	0	4	0	1	92	24	56
05	81/1	922	546	2	51	0	5	6	2	229	46	35
06	81/1	958	794	8	6	0	2	0	10	50	4	84
17	81/1	1084	798	39	25	0	8	0	8	61	29	116
26	81/1	1092	840	10	14	0	27	2	0	139	31	29
16	81/1	1134	565	4	0	0	44	0	25	335	1	160
23	81/1	1140	989	5	9	0	3	0	0	57	0	77
12	81/1	1240	1102	11	12	0	3	0	0	48	19	45
02	81/1	1342	709	19	4	0	22	0	3	430	35	120
21	81/1	1385	978	1	0	0	8	1	1	179	43	174
09	81/1	1437	1074	3	0	0	14	0	8	210	12	116
30	81/1	1724	1358	17	17	0	14	4	5	155	49	105
14	81/1	1977	1293	98	168	0	20	3	10	157	25	203
28	81/1	2107	1790	20	15	0	5	1	5	193	12	66
32	81/1	2246	1762	48	39	0	72	4	9	165	28	119
22	81/1	2303	1801	158	21	0	6	2	4	141	27	143
03	81/1	2410	1888	1	181	0	10	0	8	164	8	150
24	81/1	2555	2131	32	25	8	10	5	5	130	41	168
20	81/1	2573	2187	31	36	0	6	0	5	129	27	152
15	81/1	2732	2405	65	74	0	17	0	6	91	5	69
18	81/1	2805	2223	4	8	0	19	3	4	339	35	170
19	81/1	2957	2693	22	2	1	3	0	9	84	17	126
11	81/1	3933	3275	41	53	0	23	2	43	195	59	242
25	81/1	4161	3502	104	17	0	40	3	7	323	5	160
04	81/1	4300	3884	10	60	0	43	1	10	100	17	175
		56150	44738	883	1057	11	457	39	230	4629	657	3449

TOTAL CHRONIC DIALYSIS PATIENTS BY TREATMENT MODALITY

Thu Apr 8 1982
SOURCE: ESRD SEMI-ANNUAL SURVEY

NETWORK	SURVEY PERIOD	TOTAL PATIENTS	STAFF-ASSISTED HEMODIALYSIS	STAFF-ASSISTED PERITONAL	IN-UNIT SELF DIALYSIS HEMODIALYSIS	IN-UNIT SELF DIALYSIS PERITONEAL	SELF-DIALYSIS TRAINING HEMODIALYSIS	SELF-DIALYSIS TRAINING PERITONEAL	SELF-DIALYSIS TRAINING CAPD	HOME PATIENTS HEMODIALYSIS	HOME PATIENTS PERITONEAL	HOME PATIENTS CAPD
01	81/2	400	192	5	132	0	11	0	2	45	0	13
08	81/2	697	502	8	0	0	5	1	2	75	19	85
13	81/2	734	481	18	40	0	3	0	4	58	4	126
31	81/2	760	575	29	45	0	1	0	5	51	22	32
29	81/2	794	677	29	0	0	0	0	0	48	0	40
27	81/2	803	651	21	9	0	3	0	1	25	0	93
10	81/2	886	680	26	0	0	1	0	0	90	19	70
07	81/2	923	689	8	0	0	2	0	1	136	12	75
05	81/2	949	613	4	29	0	0	0	1	225	39	38
06	81/2	987	810	4	4	0	0	2	5	49	5	108
26	81/2	1149	862	20	35	0	24	1	4	130	30	43
17	81/2	1161	862	38	22	0	7	0	3	51	12	166
16	81/2	1217	649	11	0	0	16	0	7	319	0	215
23	81/2	1234	1062	5	22	0	1	0	0	53	8	83
12	81/2	1290	1152	8	13	0	4	5	0	48	15	45
21	81/2	1448	1051	3	0	0	10.	1	1	169	33	180
02	81/2	1460	798	34	4	0	16	0	5	432	28	143
09	81/2	1546	1144	6	0	0	16	0	6	199	13	162
30	81/2	1795	1413	24	16	0	7	1	2	141	54	137
14	81/2	2004	1438	90	25	0	13	0	8	158	24	248
28	81/2	2174	1847	20	12	0	5	2	0	186	12	9
32	81/2	2355	1823	72	73	0	32	5	2	169	27	152
22	81/2	2408	1857	152	21	0	5	0	4	125	39	205
03	81/2	2455	2003	1	80	0	18	0	5	160	5	183
24	81/2	2636	2173	22	34	7	11	7	5	130	45	202
20	81/2	2791	2356	30	37	3	6	0	3	139	19	198
15	81/2	2825	2459	73	76	0	22	0	2	90	9	94
18	81/2	3011	2380	4	7	0	18	0	4	329	50	219
19	81/2	3250	2946	20	6	0	3	0	8	72	15	180
11	81/2	4125	3416	37	82	0	15	0	15	200	65	295
25	81/2	4303	3641	80	27	0	30	0	24	305	5	191
04	81/2	4508	4035	8	66	0	47	1	4	93	14	240
		59078	47237	910	917	10	352	26	133	4500	642	4351

MEDICARE STATUS
END OF SURVEY PERIOD

NETWORK	SURVEY PERIOD	MEDICARE NUMBER	MEDICARE PERCENT	PENDING NUMBER	PENDING PERCENT	NON-MEDICARE NUMBER	NON-MEDICARE PERCENT	TOTAL NUMBER	TOTAL PERCENT
06	80/1	599	.74	63	.08	143	.18	805	1.00
23	80/1	767	.77	67	.07	164	.16	998	1.00
29	80/1	532	.79	47	.07	94	.14	673	1.00
05	80/1	662	.79	57	.07	114	.14	833	1.00
17	80/1	769	.80	115	.12	74	.08	958	1.00
30	80/1	1204	.80	112	.07	186	.12	1502	.99
10	80/1	585	.81	45	.06	90	.12	720	.99
01	80/1	293	.81	25	.07	45	.12	363	1.00
03	80/1	1778	.82	173	.08	228	.10	2179	1.00
20	80/1	1768	.83	194	.09	161	.08	2123	1.00
08	80/1	468	.83	51	.09	46	.08	565	1.00
12	80/1	910	.84	86	.08	93	.09	1089	1.01
04	80/1	3318	.84	316	.08	297	.08	3931	1.00
02	80/1	1079	.84	103	.08	100	.08	1282	1.00
14	80/1	1470	.84	175	.10	103	.06	1748	1.00
15	80/1	2146	.85	246	.10	126	.05	2518	1.00
26	80/1	842	.85	104	.11	44	.04	990	1.00
18	80/1	2080	.85	248	.10	112	.05	2440	1.00
31	80/1	488	.86	69	.12	11	.02	568	1.00
16	80/1	862	.86	56	.06	81	.08	999	1.00
22	80/1	1764	.86	178	.09	98	.05	2040	1.00
25	80/1	3232	.86	212	.06	312	.08	3756	1.00
11	80/1	2940	.87	270	.08	187	.06	3397	1.01
07	80/1	629	.87	77	.11	15	.02	721	1.00
24	80/1	1997	.87	150	.07	159	.07	2306	1.01
21	80/1	1032	.87	121	.10	33	.03	1186	1.00
13	80/1	575	.89	58	.09	13	.02	646	1.00
27	80/1	632	.90	34	.05	33	.05	699	1.00
19	80/1	2332	.90	159	.06	108	.04	2599	1.00
28	80/1	1709	.90	101	.05	90	.05	1900	1.00
32	80/1	1768	.90	98	.05	109	.06	1975	1.01
09	80/1	1144	.91	62	.05	58	.05	1264	1.01
		42374		3872		3527		49773	

MEDICARE STATUS
END OF SURVEY PERIOD

NETWORK	SURVEY PERIOD	MEDICARE NUMBER	MEDICARE PERCENT	PENDING NUMBER	PENDING PERCENT	NON-MEDICARE NUMBER	NON-MEDICARE PERCENT	TOTAL NUMBER	TOTAL PERCENT
06	80/2	644	.74	62	.07	165	.19	871	1.00
23	80/2	795	.75	50	.05	220	.21	1065	1.01
29	80/2	556	.78	65	.09	89	.13	710	1.00
10	80/2	624	.79	67	.09	97	.12	788	1.00
05	80/2	709	.80	49	.06	127	.14	885	1.00
02	80/2	1145	.83	169	.12	62	.05	1376	1.00
03	80/2	1873	.83	168	.07	216	.10	2257	1.00
01	80/2	312	.83	22	.06	42	.11	376	1.00
08	80/2	505	.84	45	.07	54	.09	604	1.00
30	80/2	1350	.84	86	.05	169	.11	1605	1.00
31	80/2	539	.84	85	.13	19	.03	643	1.00
22	80/2	1842	.84	204	.09	135	.06	2181	.99
17	80/2	812	.84	98	.10	58	.06	968	1.00
04	80/2	3467	.85	313	.08	314	.08	4094	1.01
12	80/2	984	.85	79	.07	95	.08	1158	1.00
14	80/2	1551	.85	168	.09	115	.06	1834	1.00
11	80/2	3141	.86	245	.07	254	.07	3640	1.00
25	80/2	3381	.86	198	.05	341	.09	3920	1.00
15	80/2	2259	.86	200	.08	172	.07	2631	1.01
20	80/2	1967	.86	165	.07	156	.07	2288	1.00
26	80/2	879	.86	91	.09	48	.05	1018	1.00
21	80/2	1115	.87	113	.09	49	.04	1277	1.00
07	80/2	652	.87	87	.12	11	.01	750	1.00
16	80/2	907	.87	65	.06	74	.07	1046	1.00
13	80/2	595	.88	64	.09	16	.02	675	.99
24	80/2	2146	.88	150	.06	138	.06	2434	1.00
27	80/2	640	.88	56	.08	31	.04	727	1.00
18	80/2	2292	.88	196	.08	106	.04	2594	1.00
28	80/2	1741	.89	109	.06	104	.05	1954	1.00
32	80/2	1837	.89	137	.07	100	.05	2074	1.01
09	80/2	1209	.90	82	.06	59	.04	1350	1.00
19	80/2	2522	.90	166	.06	127	.05	2815	1.01
		44991		3854		3763		52608	

MEDICARE STATUS
END OF SURVEY PERIOD

NETWORK	SURVEY PERIOD	MEDICARE NUMBER	MEDICARE PERCENT	PENDING NUMBER	PENDING PERCENT	NON-MEDICARE NUMBER	NON-MEDICARE PERCENT	TOTAL NUMBER	TOTAL PERCENT
06	81/1	738	.77	43	.04	177	.18	958	.99
23	81/1	886	.78	35	.03	219	.19	1140	1.00
17	81/1	869	.80	139	.13	76	.07	1084	1.00
12	81/1	1005	.81	123	.10	112	.09	1240	1.00
01	81/1	308	.83	21	.06	41	.11	370	1.00
10	81/1	718	.85	41	.05	82	.10	841	1.00
05	81/1	782	.85	37	.04	103	.11	922	1.00
08	81/1	541	.85	41	.06	51	.08	633	.99
29	81/1	631	.85	67	.09	44	.06	742	1.00
02	81/1	1158	.86	141	.11	43	.03	1342	1.00
03	81/1	2080	.86	110	.05	220	.09	2410	1.00
16	81/1	973	.86	80	.07	81	.07	1134	1.00
15	81/1	2356	.86	203	.07	173	.06	2732	.99
14	81/1	1700	.86	176	.09	101	.05	1977	1.00
07	81/1	720	.86	102	.12	13	.02	835	1.00
30	81/1	1483	.86	78	.05	163	.09	1724	1.00
11	81/1	3403	.87	261	.07	269	.07	3933	1.01
04	81/1	3726	.87	291	.07	283	.07	4300	1.01
25	81/1	3646	.88	144	.03	358	.09	4148	1.00
20	81/1	2254	.88	153	.06	166	.06	2573	1.00
13	81/1	656	.88	64	.09	22	.03	742	1.00
26	81/1	961	.88	92	.08	39	.04	1092	1.00
31	81/1	623	.88	53	.07	35	.05	711	1.00
24	81/1	2261	.88	165	.06	129	.05	2555	.99
22	81/1	2028	.88	147	.06	128	.06	2303	1.00
32	81/1	1972	.88	166	.07	108	.05	2246	1.00
27	81/1	679	.89	52	.07	28	.04	759	1.00
09	81/1	1298	.90	88	.06	51	.04	1437	1.00
18	81/1	2516	.90	157	.06	132	.05	2805	1.01
21	81/1	1259	.91	73	.05	53	.04	1385	1.00
19	81/1	2696	.91	138	.05	123	.04	2957	1.00
28	81/1	1917	.91	115	.05	75	.04	2107	1.00
		48843		3596		3698		56137	

MEDICARE STATUS
END OF SURVEY PERIOD

NETWORK	SURVEY PERIOD	MEDICARE NUMBER	MEDICARE PERCENT	PENDING NUMBER	PENDING PERCENT	NON-MEDICARE NUMBER	NON-MEDICARE PERCENT	TOTAL NUMBER	TOTAL PERCENT
23	81/2	927	.75	85	.07	222	.18	1234	1.00
06	81/2	766	.78	48	.05	173	.18	987	1.01
17	81/2	915	.79	175	.15	71	.06	1161	1.00
07	81/2	754	.82	143	.15	26	.03	923	1.00
01	81/2	338	.84	18	.04	44	.11	400	.99
12	81/2	1099	.85	104	.08	87	.07	1290	1.00
10	81/2	751	.85	52	.06	83	.09	886	1.00
14	81/2	1708	.85	166	.08	130	.06	2004	.99
29	81/2	678	.85	56	.07	60	.06	794	1.00
30	81/2	1548	.86	70	.04	177	.10	1795	1.00
25	81/2	3710	.86	218	.05	370	.09	4298	1.00
08	81/2	606	.87	35	.05	56	.08	697	1.00
11	81/2	3590	.87	285	.07	250	.06	4125	1.00
04	81/2	3908	.87	276	.06	324	.07	4508	1.00
15	81/2	2446	.87	218	.08	161	.06	2825	1.01
02	81/2	1266	.87	72	.05	122	.08	1460	1.00
22	81/2	2101	.87	187	.08	120	.05	2408	1.00
05	81/2	837	.88	50	.05	62	.07	949	1.00
03	81/2	2159	.88	120	.05	176	.07	2455	1.00
26	81/2	1011	.88	99	.09	39	.03	1149	1.00
21	81/2	1273	.88	112	.08	63	.04	1448	1.00
16	81/2	1080	.89	61	.05	76	.06	1217	1.00
31	81/2	680	.89	52	.07	28	.04	760	1.00
20	81/2	2473	.89	144	.05	174	.06	2791	1.00
09	81/2	1392	.90	106	.07	48	.03	1546	1.00
24	81/2	2371	.90	140	.05	125	.05	2636	1.00
13	81/2	658	.90	54	.07	22	.03	734	1.00
28	81/2	1953	.90	110	.05	111	.05	2174	1.00
18	81/2	2696	.90	186	.06	129	.04	3011	1.00
19	81/2	2943	.91	149	.05	158	.05	3250	1.01
27	81/2	729	.91	47	.06	27	.03	803	1.00
32	81/2	2146	.91	127	.05	82	.03	2355	.99
		51512		3765		3796		59073	

NUMBER OF LIVING CHRONIC MAINTENANCE DIALYSIS PATIENTS PER MILLION POPULATION AS OF DECEMBER 31, 1980-1981

Thu Apr 8 1982 SOURCE: ESRD SEMI-ANNUAL SURVEY

NETWORK	YEAR	PATIENTS PER MILLION	NETWORK	YEAR	PATIENTS PER MILLION
08	1980	71.39	08	1981	82.39
07	1980	128.64	07	1981	158.32
13	1980	146.74	13	1981	160.61
10	1980	151.54	02	1981	164.41
02	1980	154.95	10	1981	170.38
17	1980	156.13	26	1981	185.32
26	1980	164.19	17	1981	187.26
22	1980	177.17	22	1981	195.61
09	1980	180.00	05	1981	197.71
05	1980	184.38	09	1981	206.13
16	1980	190.53	16	1981	221.68
18	1980	216.17	03	1981	236.74
21	1980	216.44	28	1981	241.56
28	1980	217.11	21	1981	245.42
03	1980	217.65	06	1981	246.75
06	1980	217.75	29	1981	248.90
27	1980	226.48	27	1981	250.16
31	1980	227.21	14	1981	250.50
29	1980	227.56	18	1981	250.92
14	1980	256.34	31	1981	268.55
11	1980	256.34	15	1981	287.39
30	1980	258.87	30	1981	289.52
15	1980	267.65	11	1981	290.49
20	1980	272.38	04	1981	314.58
19	1980	278.44	32	1981	319.97
32	1980	281.79	19	1981	321.46
04	1980	285.69	12	1981	322.50
12	1980	289.50	24	1981	323.04
24	1980	298.28	20	1981	332.26
25	1980	329.41	25	1981	361.60
23	1980	338.10	23	1981	388.05
01	1980	376.00	01	1981	400.00

TOTAL HOME PATIENTS DIVIDED BY TOTAL PATIENTS RECEIVING CARE AT END OF SURVEY PERIOD

Thu Apr 8 1982 SOURCE: ESRD SEMI-ANNUAL SURVEY

NETWORK	SURVEY PERIOD	TOTAL HOME PTS 21+22+23	TOTAL PATIENTS 14-23 SUMMED	RATIO HOME PATIENTS 21+22+23/14-23 SUMMED
04	80/1	207	3931	.05
	80/1	120	2518	.05
	80/1	55	998	.06
	80/1	81	1089	.07
	80/1	186	2599	.07
	80/1	331	3756	.09
	80/1	63	673	.09
	80/1	63	699	.09
	80/1	201	2179	.09
	80/1	350	3397	.10
	80/1	219	2123	.10
	80/1	191	1900	.10
	80/1	230	2040	.11
	80/1	99	805	.12
	80/1	269	2306	.12
	80/1	70	568	.12
	80/1	129	958	.13
	80/1	260	1975	.13
	80/1	271	1748	.16
	80/1	126	720	.17
	80/1	169	990	.17
	80/1	445	2440	.18
	80/1	281	1519	.18
	80/1	73	363	.20
	80/1	137	646	.21
	80/1	300	1264	.24
	80/1	134	565	.24
	80/1	318	1186	.27
	80/1	199	721	.28
	80/1	253	833	.30
	80/1	442	999	.44
	80/1	571	1282	.45
		6843	49790	.14

TOTAL HOME PATIENTS DIVIDED BY TOTAL PATIENTS RECEIVING CARE AT
END OF SURVEY PERIOD

Thu Apr 8 1982 SOURCE: ESRD SEMI-ANNUAL SURVEY

NETWORK	SURVEY PERIOD	TOTAL HOME PTS 21+22+23	TOTAL PATIENTS 14-23 SUMMED	RATIO HOME PATIENTS 21+22+23/14-23 SUMMED
	80/2	132	2631	.05
04	80/2	252	4094	.06
	80/2	213	2815	.08
	80/2	95	1158	.08
	80/2	71	710	.10
	80/2	234	2288	.10
	80/2	415	3920	.11
	80/2	79	727	.11
	80/2	249	2257	.11
	80/2	263	2181	.12
	80/2	300	2434	.12
	80/2	226	1954	.12
	80/2	123	1065	.12
	80/2	80	643	.12
	80/2	422	3640	.12
	80/2	264	2074	.13
	80/2	127	871	.15
	80/2	146	968	.15
	80/2	173	1018	.17
	80/2	279	1605	.17
	80/2	66	376	.18
	80/2	330	1834	.18
	80/2	490	2594	.19
	80/2	150	788	.19
	80/2	161	675	.24
	80/2	322	1350	.24
	80/2	149	604	.25
	80/2	197	750	.26
	80/2	354	1277	.28
	80/2	311	885	.35
	80/2	452	1046	.43
	80/2	621	1376	.45
		7746	52608	.15

TOTAL HOME PATIENTS DIVIDED BY TOTAL PATIENTS RECEIVING CARE AT
END OF SURVEY PERIOD
Thu Apr 8 1982 SOURCE: ESRD SEMI-ANNUAL SURVEY

NETWORK	SURVEY PERIOD	TOTAL HOME PTS 21+22+23	TOTAL PATIENTS 14-23 SUMMED	RATIO HOME PATIENTS 21+22+23/14-23 SUMMED
	81/1	165	2732	.06
04	81/1	292	4300	.07
	81/1	227	2957	.08
	81/1	112	1240	.09
	81/1	81	742	.11
	81/1	81	759	.11
	81/1	308	2573	.12
	81/1	488	4161	.12
	81/1	134	1140	.12
	81/1	339	2555	.13
	81/1	271	2107	.13
	81/1	322	2410	.13
	81/1	94	711	.13
	81/1	496	3933	.13
	81/1	138	958	.14
	81/1	311	2303	.14
	81/1	312	2246	.14
	81/1	60	370	.16
	81/1	199	1092	.18
	81/1	309	1724	.18
	81/1	206	1084	.19
	81/1	544	2805	.19
	81/1	385	1977	.19
	81/1	172	841	.20
	81/1	338	1437	.24
	81/1	155	633	.24
	81/1	183	742	.25
	81/1	226	835	.27
	81/1	396	1385	.29
	81/1	310	922	.34
	81/1	585	1342	.44
	81/1	496	1134	.44
		8735	56150	.16

TOTAL HOME PATIENTS DIVIDED BY TOTAL PATIENTS RECEIVING CARE AT END OF SURVEY PERIOD

Thu Apr 8 1982 SOURCE: ESRD SEMI-ANNUAL SURVEY

NETWORK	SURVEY PERIOD	TOTAL HOME PTS 21+22+23	TOTAL PATIENTS 14-23 SUMMED	RATIO HOME PATIENTS 21+22+23/14-23 SUMMED
	81/2	193	2825	.07
04	81/2	347	4508	.08
	81/2	267	3250	.08
	81/2	108	1290	.08
	81/2	88	794	.11
	81/2	501	4303	.12
	81/2	144	1234	.12
	81/2	356	2791	.13
	81/2	288	2174	.13
	81/2	377	2636	.14
	81/2	58	400	.14
	81/2	560	4125	.14
	81/2	348	2455	.14
	81/2	105	760	.14
	81/2	369	2408	.15
	81/2	348	2355	.15
	81/2	118	803	.15
	81/2	162	987	.16
	81/2	203	1149	.18
	81/2	332	1795	.18
	81/2	229	1161	.20
	81/2	598	3011	.20
	81/2	179	886	.20
	81/2	430	2004	.21
	81/2	374	1546	.24
	81/2	223	923	.24
	81/2	382	1448	.26
	81/2	179	697	.26
	81/2	188	734	.26
	81/2	302	949	.32
	81/2	603	1460	.41
	81/2	534	1217	.44
		9493	59078	.16

NEW PATIENTS PER MILLION POPULATION BEGINNING A COURSE OF CHRONIC DIALYSIS THERAPY BY NETWORK, 1980-1981

Thu Apr 8 1982 SOURCE: ESRD SEMI-ANNUAL SURVEY

NETWORK	YEAR	PATIENTS PER MILLION	NETWORK	YEAR	PATIENTS PER MILLION
08	1980	29.20	08	1981	33.92
02	1980	58.90	02	1981	59.57
16	1980	61.20	05	1981	65.83
07	1980	66.04	13	1981	67.61
09	1980	66.27	10	1981	72.69
26	1980	66.94	26	1981	72.74
13	1980	66.96	28	1981	74.11
22	1980	69.78	17	1981	74.84
05	1980	70.42	09	1981	77.60
28	1980	75.11	22	1981	79.12
18	1980	76.92	03	1981	82.55
10	1980	78.46	16	1981	82.88
03	1980	79.46	07	1981	85.76
31	1980	82.33	21	1981	86.10
11	1980	82.82	27	1981	86.60
14	1980	82.82	18	1981	86.92
27	1980	83.80	14	1981	96.13
17	1980	85.32	06	1981	96.50
21	1980	85.42	11	1981	96.90
15	1980	89.83	30	1981	97.90
30	1980	93.55	31	1981	104.24
29	1980	93.91	25	1981	109.92
06	1980	98.25	04	1981	110.33
20	1980	100.00	20	1981	110.60
04	1980	101.05	15	1981	111.29
12	1980	104.25	19	1981	118.30
25	1980	105.71	01	1981	119.00
19	1980	105.74	29	1981	120.69
01	1980	111.00	12	1981	124.00
32	1980	114.81	32	1981	124.59
23	1980	117.46	24	1981	125.37
24	1980	131.99	23	1981	143.71

TOTAL HOME SELF DIALYSIS PATIENTS COMPLETING TRAINING DIVIDED BY "STARTED FIRST TIME EVER"

Thu Apr 8 1982 SOURCE: ESRD SEMI-ANNUAL SURVEY

NETWORK	SURVEY PERIOD	HOME SELF TRAINED 29+31+33	NEWSTARTS (04A+04B/2)	RATIO OF HOME SELF TRAINED TO NEWSTARTS
	80/1	10	105.50	.09
	80/1	45	316.50	.14
	80/1	17	103.00	.17
	80/1	36	173.50	.21
	80/1	58	233.50	.25
	80/1	52	207.00	.25
	80/1	71	285.50	.25
	80/1	44	159.00	.28
	80/1	84	300.50	.28
	80/1	62	210.50	.29
	80/1	67	214.00	.31
04	80/1	111	362.50	.31
	80/1	36	95.50	.38
	80/1	30	75.00	.40
	80/1	116	281.00	.41
	80/1	47	108.00	.44
	80/1	21	47.50	.44
	80/1	27	61.00	.44
	80/1	102	225.00	.45
	80/1	45	96.00	.47
	80/1	77	154.50	.50
	80/1	126	247.50	.51
	80/1	89	175.50	.51
	80/1	52	94.50	.55
	80/1	79	129.50	.61
	80/1	45	73.00	.62
	80/1	40	63.50	.63
	80/1	64	97.00	.66
	80/1	19	28.50	.67
	80/1	123	132.00	.93
	80/1	128	123.00	1.04
	80/1	109	88.00	1.24
		2032	5066.50	.40

TOTAL HOME SELF DIALYSIS PATIENTS COMPLETING TRAINING
DIVIDED BY "STARTED FIRST TIME EVER"
Thu Apr 8 1982 SOURCE: ESRD SEMI-ANNUAL SURVEY

NETWORK	SURVEY PERIOD	HOME SELF TRAINED 29+31+33	NEWSTARTS (04A+04B/2)	RATIO OF HOME SELF TRAINED TO NEWSTARTS
	80/2	23	103.00	.22
	80/2	47	208.00	.23
	80/2	69	249.00	.28
04	80/2	103	361.50	.28
	80/2	21	73.50	.29
	80/2	61	209.50	.29
	80/2	66	197.50	.33
	80/2	25	71.50	.35
	80/2	10	27.00	.37
	80/2	91	238.00	.38
	80/2	86	215.50	.40
	80/2	65	164.50	.40
	80/2	125	307.00	.41
	80/2	29	69.00	.42
	80/2	47	108.50	.43
	80/2	44	99.50	.44
	80/2	102	205.00	.50
	80/2	53	95.50	.55
	80/2	55	100.50	.55
	80/2	62	105.50	.59
	80/2	80	135.50	.59
	80/2	76	119.00	.64
	80/2	199	312.50	.64
	80/2	118	176.00	.67
	80/2	41	60.00	.68
	80/2	57	82.00	.70
	80/2	159	214.00	.74
	80/2	58	74.50	.78
	80/2	64	81.00	.79
	80/2	138	138.50	1.00
	80/2	136	120.00	1.13
	80/2	106	80.00	1.32
		2416	4802.00	.50

TOTAL HOME SELF DIALYSIS PATIENTS COMPLETING TRAINING DIVIDED BY "STARTED FIRST TIME EVER"

Thu Apr 8 1982 SOURCE: ESRD SEMI-ANNUAL SURVEY

NETWORK	SURVEY PERIOD	HOME SELF TRAINED 29+31+33	NEWSTARTS (04A+04B/2)	RATIO OF HOME SELF TRAINED TO NEWSTARTS
	81/1	45	278.00	.16
	81/1	72	305.00	.24
	81/1	7	28.50	.25
	81/1	38	136.00	.28
	81/1	52	184.00	.28
	81/1	29	93.50	.31
	81/1	113	340.00	.33
	81/1	29	76.50	.38
	81/1	45	112.50	.40
	81/1	64	157.00	.41
	81/1	94	225.00	.42
	81/1	106	244.50	.43
	81/1	110	243.00	.45
	81/1	49	100.00	.49
	81/1	172	354.00	.49
	81/1	128	259.50	.49
	81/1	112	223.00	.50
	81/1	52	102.00	.51
04	81/1	208	402.50	.52
	81/1	64	117.00	.55
	81/1	63	110.50	.57
	81/1	82	139.50	.59
	81/1	152	253.50	.60
	81/1	45	73.50	.61
	81/1	43	69.50	.62
	81/1	137	204.50	.67
	81/1	84	124.00	.68
	81/1	89	121.50	.73
	81/1	68	82.00	.83
	81/1	67	74.50	.90
	81/1	124	129.00	.96
	81/1	145	115.50	1.26
		2688	5479.00	.49

TOTAL HOME SELF DIALYSIS PATIENTS COMPLETING TRAINING
DIVIDED BY "STARTED FIRST TIME EVER"

Thu Apr 8 1982 SOURCE: ESRD SEMI-ANNUAL SURVEY

NETWORK	SURVEY PERIOD	HOME SELF TRAINED 29+31+33	NEWSTARTS (04A+04B/2)	RATIO OF HOME SELF TRAINED TO NEWSTARTS
	81/2	2	99.00	.02
	81/2	16	112.00	.14
	81/2	42	269.00	.16
	81/2	8	31.00	.26
04	81/2	123	388.00	.32
	81/2	103	314.00	.33
	81/2	45	133.00	.34
	81/2	39	116.00	.34
	81/2	91	252.00	.36
	81/2	106	293.00	.36
	81/2	57	149.50	.38
	81/2	32	83.50	.38
	81/2	97	239.50	.41
	81/2	91	205.00	.44
	81/2	55	115.00	.48
	81/2	161	334.00	.48
	81/2	34	71.00	.48
	81/2	37	72.50	.51
	81/2	135	242.50	.56
	81/2	90	146.50	.61
	81/2	76	125.00	.61
	81/2	44	70.00	.63
	81/2	176	268.00	.66
	81/2	60	91.00	.66
	81/2	145	215.50	.67
	81/2	50	69.50	.72
	81/2	65	89.00	.73
	81/2	81	110.50	.73
	81/2	117	151.50	.77
	81/2	148	180.00	.82
	81/2	145	140.50	1.03
	81/2	120	112.00	1.07
		2591	5288.50	.49

TOTAL PATIENTS TRANSPLANTED
DIVIDED BY TOTAL POOL

Thu Apr 8 1982 SOURCE:ESRD SEMI-ANNUAL SURVEY

NETWORK	SURVEY PERIOD	TOTAL TRANSPLANTS (10A+10B)	TOTAL POOL (01+02+(04A+04B/2))	RATIO OF TRANSPLANT TO TOTAL POOL
	80/1	9.00	682.00	.01
	80/1	64.00	2691.50	.02
	80/1	8.00	381.50	.02
	80/1	48.00	2110.50	.02
	80/1	85.00	3798.50	.02
	80/1	29.00	1041.00	.03
	80/1	30.00	858.50	.03
	80/1	80.00	2640.50	.03
	80/1	35.00	1172.00	.03
	80/1	93.00	3409.00	.03
	80/1	24.00	825.00	.03
	80/1	67.00	2521.50	.03
	80/1	22.00	731.00	.03
	80/1	63.00	2046.00	.03
04	80/1	125.00	4059.50	.03
	80/1	51.00	1305.00	.04
	80/1	79.00	1776.50	.04
	80/1	62.00	1565.50	.04
	80/1	22.00	603.50	.04
	80/1	42.00	1087.50	.04
	80/1	84.00	2190.00	.04
	80/1	71.00	1291.50	.05
	80/1	123.00	2486.50	.05
	80/1	40.00	804.50	.05
	80/1	115.00	2160.00	.05
	80/1	51.00	1031.00	.05
	80/1	97.00	1991.50	.05
	80/1	58.00	1051.00	.06
	80/1	47.00	577.50	.08
	80/1	65.00	706.00	.09
	80/1	99.00	1001.00	.10
	80/1	97.00	770.00	.13
		1985.00	51366.50	.04

TOTAL PATIENTS TRANSPLANTED
DIVIDED BY TOTAL POOL

Thu Apr 8 1982 SOURCE:ESRD SEMI-ANNUAL SURVEY

NETWORK	SURVEY PERIOD	TOTAL TRANSPLANTS (10A+10B)	TOTAL POOL (01+02+(04A+04B/2))	RATIO OF TRANSPLAN TO TOTAL POOL
	80/2	9.00	714.50	.01
	80/2	55.00	2332.50	.02
	80/2	64.00	2855.00	.02
	80/2	8.00	392.00	.02
	80/2	94.00	4054.50	.02
	80/2	27.00	829.50	.03
	80/2	25.00	905.50	.03
	80/2	79.00	2588.00	.03
	80/2	37.00	1095.00	.03
	80/2	38.00	1191.00	.03
	80/2	102.00	3696.00	.03
	80/2	37.00	1074.00	.03
04	80/2	112.00	4244.50	.03
	80/2	63.00	2172.50	.03
	80/2	52.00	1306.00	.04
	80/2	108.00	2728.00	.04
	80/2	86.00	2384.00	.04
	80/2	99.00	2654.00	.04
	80/2	33.00	772.50	.04
	80/2	69.00	1692.50	.04
	80/2	63.00	1383.00	.05
	80/2	74.00	1411.50	.05
	80/2	42.00	907.50	.05
	80/2	118.00	2275.50	.05
	80/2	53.00	1089.50	.05
	80/2	109.00	2037.50	.05
	80/2	96.00	1924.00	.05
	80/2	41.00	639.00	.06
	80/2	71.00	1061.50	.07
	80/2	61.00	728.00	.08
	80/2	57.00	629.00	.09
	80/2	109.00	818.50	.13
		2091.00	54586.00	.04

TOTAL PATIENTS TRANSPLANTED
DIVIDED BY TOTAL POOL

Thu Apr 8 1982 SOURCE:ESRD SEMI-ANNUAL SURVEY

NETWORK	SURVEY PERIOD	TOTAL TRANSPLANTS (10A+10B)	TOTAL POOL (01+02+(04A+04B/2))	RATIO OF TRANSPLANT TO TOTAL POOL
	81/1	11.00	803.50	.01
	81/1	41.00	2508.00	.02
	81/1	60.00	3113.00	.02
	81/1	50.00	2317.00	.02
	81/1	9.00	404.50	.02
	81/1	88.00	4262.00	.02
	81/1	99.00	2850.50	.03
	81/1	28.00	973.00	.03
	81/1	117.00	4008.00	.03
	81/1	27.00	888.00	.03
	81/1	83.00	2480.00	.03
	81/1	36.00	1294.00	.03
	81/1	39.00	1406.00	.03
	81/1	49.00	1768.00	.03
	81/1	25.00	796.50	.03
	81/1	78.00	2708.50	.03
04	81/1	155.00	4497.50	.03
	81/1	40.00	1162.50	.03
	81/1	40.00	966.50	.04
	81/1	52.00	1159.50	.04
	81/1	111.00	2907.00	.04
	81/1	26.00	698.50	.04
	81/1	67.00	1393.00	.05
	81/1	111.00	2037.50	.05
	81/1	59.00	1094.50	.05
	81/1	54.00	1141.50	.05
	81/1	84.00	1489.50	.06
	81/1	127.00	2128.00	.06
	81/1	46.00	762.00	.06
	81/1	134.00	2427.50	.06
	81/1	51.00	676.50	.08
	81/1	96.00	883.00	.11
		2093.00	58005.00	.04

TOTAL PATIENTS TRANSPLANTED
DIVIDED BY TOTAL POOL

Thu Apr 8 1982 SOURCE:ESRD SEMI-ANNUAL SURVEY

NETWORK	SURVEY PERIOD	TOTAL TRANSPLANTS (10A+10B)	TOTAL POOL (01+02+(04A+04B/2))	RATIO OF TRANSPLANT TO TOTAL POOL
	81/2	4.00	401.00	.01
	81/2	22.00	930.00	.02
	81/2	81.00	3250.00	.02
	81/2	54.00	2828.50	.02
	81/2	16.00	841.00	.02
	81/2	94.00	4471.00	.02
	81/2	32.00	1049.00	.03
	81/2	95.00	2809.00	.03
	81/2	121.00	4233.00	.03
	81/2	53.00	1863.50	.03
	81/2	88.00	2605.00	.03
	81/2	35.00	1352.00	.03
	81/2	30.00	987.50	.03
	81/2	65.00	2456.50	.03
	81/2	24.00	827.50	.03
04	81/2	130.00	4688.00	.03
	81/2	44.00	1510.00	.03
	81/2	108.00	3073.00	.04
	81/2	112.00	3014.00	.04
	81/2	46.00	1249.00	.04
	81/2	29.00	787.00	.04
	81/2	92.00	2249.50	.04
	81/2	55.00	1198.50	.05
	81/2	67.00	1475.50	.05
	81/2	57.00	1264.00	.05
	81/2	64.00	1208.00	.05
	81/2	37.00	698.00	.05
	81/2	88.00	1588.50	.06
	81/2	135.00	2425.50	.06
	81/2	132.00	2157.00	.06
	81/2	70.00	808.50	.09
	81/2	109.00	968.00	.11
		2189.00	61266.50	.04

Fri Apr 9 1982
SOURCE: ESRD SEMI-ANNUAL SURVEY

UNADJUSTED ANNUAL MORTALITY OF DIALYSIS PATIENTS
BASED ON SEMI-ANNUAL SURVEY

NETWORK	SURVEY PERIOD	PATIENTS RECEIVING CARE BEGINNING PERIOD IN-UNIT	HOME	TOTAL	NEW PTS AT RISK (04A+04B/2)	POP. AT RISK (01+02+(1/2 NS))	TOTAL DEATHS (08A+08B)	MORTALITY RATE
	1980	539	404	943	168.00	1111.00	156	.14041
	1980	496	177	673	192.50	865.50	123	.14211
	1980	1837	402	2239	461.50	2700.50	394	.14589
	1980	479	77	556	116.50	672.50	101	.15018
	1980	900	262	1162	248.50	1410.50	215	.15242
	1980	1694	206	1900	420.00	2320.00	356	.15344
	1980	398	116	514	123.50	637.50	105	.16470
	1980	1648	170	1818	338.00	2156.00	356	.16512
	1980	2313	94	2407	441.50	2848.50	471	.16535
	1980	2818	310	3128	588.00	3716.00	640	.17222
	1980	529	235	764	169.00	933.00	161	.17256
	1980	890	48	938	185.00	1123.00	196	.17453
	1980	3199	283	3482	629.00	4111.00	725	.17635
	1980	898	84	982	208.50	1190.50	210	.17639
	1980	771	269	1040	252.00	1292.00	230	.17801
	1980	2245	161	2406	534.50	2940.50	531	.18058
	1980	635	547	1182	261.50	1443.50	261	.18081
	1980	284	69	353	55.50	408.50	74	.18115
	1980	1797	186	1983	412.00	2395.00	437	.18246
04	1980	3537	160	3697	724.00	4421.00	812	.18366
	1980	624	46	670	134.50	804.50	153	.19018
	1980	775	168	943	207.50	1150.50	220	.19122
	1900	1141	270	1411	290.00	1701.00	329	.19341
	1980	1968	253	2221	538.50	2759.50	544	.19713
	1980	1382	219	1601	351.50	1952.50	393	.20128
	1980	1586	235	1821	422.50	2243.50	463	.20637
	1980	505	128	633	154.00	787.00	170	.21601
	1980	650	79	729	196.50	925.50	201	.21717
	1980	555	52	607	146.50	753.50	165	.21897
	1980	1735	211	1946	429.50	2375.50	527	.22184
	1980	730	112	842	264.50	1106.50	269	.24310
	1980	588	121	709	204.00	913.00	242	.26506
		40146	6154	46300	9868.50	56168.50	10230	.18213

Fri Apr 9 1982
SOURCE: ESRD SEMI-ANNUAL SURVEY

UNADJUSTED ANNUAL MORTALITY OF DIALYSIS PATIENTS
BASED ON SEMI-ANNUAL SURVEY

NETWORK	SURVEY PERIOD	PATIENTS RECEIVING CARE BEGINNING PERIOD IN-UNIT	HOME	TOTAL	NEW PTS AT RISK (04A+04B/2)	POP. AT RISK (01+02+(1/2 NS))	TOTAL DEATHS (08A+08B)	MORTALITY RATE
	1981	560	198	766	250.00	1016.00	140	.13779
	1981	940	107	1047	278.50	1275.50	198	.15523
	1981	3507	415	3922	654.00	4576.00	753	.16455
	1981	585	462	1047	227.50	1274.50	210	.16477
	1981	2043	240	2283	464.50	2747.50	453	.16487
	1981	923	354	1277	254.00	1531.00	253	.16525
	1981	1717	227	1944	333.50	2277.50	382	.16772
	1981	717	552	1269	264.50	1533.50	260	.16954
	1981	3225	429	3654	688.00	4342.00	740	.17042
	1981	2151	298	2449	511.50	2960.50	513	.17328
	1981	1028	322	1350	291.00	1641.00	285	.17367
	1981	2485	144	2629	547.00	3176.00	552	.17380
	1981	310	66	376	59.50	435.50	77	.17680
	1981	1324	287	1611	303.50	1914.50	341	.17811
	1981	2596	212	2808	598.00	3406.00	611	.17938
	1981	2107	490	2597	521.50	3118.50	566	.18149
	1981	1994	263	2257	428.00	2685.00	493	.18361
	1981	537	85	622	147.50	769.50	142	.18453
	1981	1810	264	2074	458.50	2532.50	468	.18479
	1981	824	149	973	232.00	1205.00	226	.18755
	1981	621	271	892	158.00	1050.00	197	.18761
	1981	1502	331	1833	384.50	2217.50	422	.19030
	1981	648	79	727	139.00	866.00	165	.19053
	1981	857	174	1031	225.50	1256.50	240	.19100
04	1981	3844	251	4095	790.50	4885.50	940	.19240
	1981	1063	95	1158	248.00	1406.00	273	.19416
	1981	454	149	603	143.50	746.50	145	.19423
	1981	516	164	680	154.50	834.50	164	.19652
	1981	744	127	871	193.00	1064.00	213	.20018
	1981	1920	263	2183	487.00	2670.00	574	.21498
	1981	638	150	788	189.00	977.00	233	.23848
	1981	639	71	710	192.50	902.50	221	.24487
		44837	7689	52526	10767.50	63293.50	11450	.18090

Form Approved
OMB No. 0938-0094

END-STAGE RENAL DISEASE MEDICAL INFORMATION SYSTEM
ESRD FACILITY SURVEY

FOR THE PERIOD

PART ONE

PATIENT LOAD

Edits:
Fields 01 + 02 = field 03
Field 03 + (04A thru 07B) − (08A thru 13B) = field 24
Sum of fields 14 thru 23 = field 24
Sum of fields 25 thru 27 = field 24

Patients Receiving Care Beginning of Survey Period		
In-Unit	Home	Total fields 01 thru 02
01	02	03

	Additions During Survey Period			
	Started for first time ever	Restored	Transferred from other dialysis unit	Returned after transplantation
In-Unit				
Home				
	04A 04B	05A 05B	06A 06B	07A 07B

Losses During Survey Period					
Deaths	Recovered kidney function	Received Transplant	Transferred to other dialysis unit	Discontinued dialysis	Other (LTFU)
08A 08B	09A 09B	10A 10B	11A 11B	12A 12B	13A 13B

Patients Receiving Care at End of Survey Period										
Staff-assisted dialysis		In-Unit Self-Dialysis		Self-Dialysis Training			Home Patients			Total
Hemodialysis	Peritoneal Dialysis	Hemodialysis	Peritoneal Dialysis	Hemodialysis	Peritoneal Dialysis	CAPD	Hemodialysis	Peritoneal Dialysis	CAPD	Fields 14 thru 23
14	15	16	17	18	19	20	21	22	23	24

Patient Eligibility Status End of Survey Period		
Currently enrolled in Medicare	Medicare application pending	Non-Medicare
25	26	27

Shifted Status (In-Unit to Home)	Shifted Status (Home to In-Unit)
28A	28B

Self-Dialysis Patients Completing Training				
Home hemodialysis	In-Unit Self Hemodialysis	Home peritoneal dialysis	In-unit self peritoneal dialysis	CAPD
29	30	31	32	33

Transient Patients	
Treated during survey period	No. of treatments during survey period
34	35

Dialysis patients awaiting transplant
36

TREATMENT LOAD

In-Unit Dialysis Treatments					
Hemodialysis			Peritoneal dialysis		
Inpatient	Outpatient Staff-Assisted	Outpatient In-Unit Self	Inpatient	Outpatient Staff-Assisted	Outpatient In-Unit Self
37	38	39	40	41	42

Dialysis Training Treatments		
Hemo-Dialysis	Peritoneal dialysis	CAPD
43	44	45

FACILITY OPERATION

Facility Operation			
Hemodialysis		Peritoneal dialysis	
Avg. shifts per week for June/Dec	Avg. oper days per week for June/Dec.	Avg. shifts per week for June/Dec.	Avg. oper days per week for June/Dec.
46	47	48	49

COMPLETED BY (Signature) | DATE | TITLE | TELEPHONE NO.

VERIFIED BY (Signature) | DATE | TITLE

REMARKS REGARDING INFORMATION PROVIDED ON THIS SURVEY SHOULD BE ENTERED ON THE LAST PAGE OF THIS SURVEY.

This report is required by law (42 USC 426; 42, CFR 405.2133). Individually identifiable patient information will not be disclosed except as provided for in the Privacy Act of 1974 (5 USC 552a; 45 CFR, Part 5a).

Form HCFA-2744 (12-80) (Formerly HCFA-900-8)

Department of Health and Human Services
Health Care Financing Administration

KENNER, LA.,
April 1, 1982.

Mr. JOHN J. SALMON,
Longworth House Office Building,
Washington, D.C.

DEAR SIR: As a dialysis patient at Ochsner Foundation Hospital, I am writing to protest the reduction in payments for dialysis costs.

At a time when all medical costs are rising, you are comtemplating a decrease in benefits for those of us who are dependent on dialysis treatments as a life support system.

We are not talking about food stamps, student loans, or cost of living adjustments, we are talking about life and death situations. How can you, in good conscience, reduce these essential benefits?

At the reduced levels you are considering, many units will be unable to stay open. This will cause additional hardships for people who are already deep in distress.

Home care versus in-unit care should remain a choice for the patient, with help from his doctor, and not influenced by cost analysis. Many patients are unable to adjust to home care and should not have to.

There are approximately 60,000 people on dialysis who have the greatest gift of all—LIFE. We can't live without it.

Please consider us.

Sincerely,

JACQUELINE HAMILTON.

Henry Ford Hospital

DETROIT, MICHIGAN 48202

April 23, 1982

Mr. John J. Salmon
Chief Counsel
Committee on Ways and Means
U.S. House of Representatives
1102 Longworth House Office Building
Washington, D.C. 20515

Dear Mr. Salmon:

As providers of Dialysis services to nearly 300 patients in Southeastern Michigan, we are disturbed by the February 12, 1982 proposed rules regarding reimbursement for ESRD services. We wish to oppose the proposed new regulations for the following reasons:

Contrary to the unsupported assumption of the Health Care Financing Administration (HCFA), we think that the impact of the proposed reimbursement system, paying 46% of hospital facilities and 28% of independent facilities less than their costs, will materially affect access to care and deprive Medicare beneficiaries their entitlements. Consequently, a very large percentage of both hospital based and independent facilities will not be able to cover their costs under the proposed system. Henry Ford Hospital services older, urban, more complicated patients. Our ESRD program will not be able to continue it its present form if the proposed rules are passed. We realize that certain providers are abusing the cost exception system and feel that those are the providers that should be restricted, not all ESRD providers.

The methodology used for the proposed rules was based on data collected from cost reporting information during the years 1977 through 1979. HCFA indirectly concedes that the 1980 average cost for outpatient hospital based treatments was $171.00. In addition, no adjustment for cost inflation was added to the proposed rates because HCFA assumes that "the provisions of dialysis services has been characterized by increased efficiencies." We believe that setting prospective rates on cost information reported 3 to 4 years ago is inappropriate. Moreover, since the proposed methodology is a prospective system, some recognition for future as well as current inflationary effects must be included.

The methodology used by HCFA in establishing the proposed rates was designed to arrive at predetermined rates dictated solely for program savings. This was not the specific intent of Congress, nor is it for the specific good of our patients. The basic premises used to determine the proposed rates seriously cloud their credibility. For instance, an arbitrary adjustment factor of 5% was used to accommodate hospitals' cost due to the possibility of the methodology failing to recognize legitimate costs. In a recent Federal subcommittee meeting, the administration of HCFA admitted the adjustment could have been 5, 10, or 20%, but 5% was chosen in the interest of cost savings. We feel that other statements in the methodology also support the arbitrary basis used to determine the proposed regulations, one such is "...the reimbursement level appears to be at an adequate level." We also question the objectivity of the methodology. In a decision memo to the secretary of HHS, two different methods of rate-setting were described by HCFA. We find it curious that both methods came up with the same rates.

In addition, the methodology used to derive the composite rate clearly is not equitable when it combines independent and hospital facilities. HCFA states, currently 10.5% of the treatments provided by independent facilities are home dialysis services. The comparable number for hospital based facilities is 23.5%, currently Henry Ford Hospital has 20.0% of our patients treated at home. By incorporating home and in-center percentages into a composite rate, the proposed regulations provide independent facilities with greater flexibility in terms of reducing composite costs by increasing the percentage of home dialysis.

HCFA admits that hospital facilities incur additional allocated overhead because the facility is subject to the Medicare hospitals financial guidelines. But the differential of $2.10 per treatment allowed for the additional allocation of hospital overhead is not realistic. Our estimate of the difference between our hospital and an independent facility is approximately $34.00 per treatment.

Not only are the cost bases for setting facility rates outdated and inadequate, but the cost information gathered by HCFA regarding home dialysis is clearly misleading. In deriving the home dialysis cost base HCFA collected data from less than 5% of ESRD programs which have home patients and included in the 5% were ten of the largest most efficient home programs. HCFA has stated that it believes 35-40% of all dialysis patients should be dialyzed at home. At Henry Ford Hospital our home patient population is between 15-20% of our total patient population. We do not believe that home dialysis is an appropriate mode of therapy for 35-40% of our population. Without trained, paid personnel in the patient's home, our patients would have to dialyze in our facility. If the cost of trained personnel were added to the cost of home dialysis, there would be no significant cost difference between home and facility treatments. Also, we take offense in that HCFA believes it can influence the numbers of patients prescribed to a certain modality by adding incentives to home dialysis reimbursement. The physician's medical opinion and the patient's own preferences dictate the modality of therapy. The new proposed reimbursement certainly will not change the patient's perference.

In regards to CAPD, HCFA has no basis to state that this modality should be the "preferred treatment for most patients." Preliminary evidence suggests that CAPD may provide an alternative for patients who are prime home hemodialysis patients so this modality will not significantly increase the percentage of home patients. Again, HCFA is premature in assessing the financial "rewards" of CAPD. Supplies represent the major cost of the CAPD treatment, with supply cost being controlled by a virtual oligopoly, the providers have a minimal price leverage.

HCFA, in addition to reducing facility reimbursement, has also proposed decreased payment be made to physicians. When the Alternative Reimbursement Method (ARM) was developed, it was intended to be reflective of a total range of services performed by a nephrologist during a monthly interval. Included in these services, besides dialysis treatment were non-dialysis, on-call, psycho-social and nutritional care of the ESRD patient. ARM was developed to recognize the level of specialist care, cognitive as well as hands-on, provided to the renal patient. The conversion factor of 20 times 13 visits was considered a relative value factor for a broad range of services, only one which related to contact of the patient while undergoing dialysis treatments. If the value factor was related to contacts as HCFA suggests, then the concept could never be adopted for home dialysis patients, since contact is rarely made with the patient during their home treatment. HCFA is attempting to reduce physician fees through a distortion of the basic concept of ARM. HCFA states that it is "assumed a physician will see the patients during every dialysis session"; if this is the case, then how can HCFA substantiate an incentive increase in payment for home dialysis patients.

Additional effects of the reduction of physician reimbursement will result in a lessening of quality care, an increase in physician non-routine service charges, and the resultant effect will be higher cost to the ESRD program.

HCFA, also, proposes that the new regulations will become effective upon publication of the final regulations without any lead time or transition period. We believe this will exaccerbate the administrative disruptions caused by the re-education of the intermediaries, providers and physicians. It is unrealistic to expect providers to adjust so abruptly to massive reductions in reimbursement without major adverse effects on patient care. We also anticipate that because of the substantial changes proposed, the reimbursement system may temporarily grind to a halt, resulting in severe cash flow problems to providers and physicians.

In the proposed regulation, HCFA mentions that periodic rate review should take place. We strongly suggest that these reviews be required annually. Since the rate-setting methodology will be tied to dynamic factors, annual reviews most assuredly will result in rate changes. Also, since the rate of individual facilities is based on an array of costs experienced by all facilities, this rate will be modified yearly.

In summary, we would like to outline the reasons we oppose passage of the proposed regulations as currently stated:

- Use of median costs by HCFA methodology results in 46% of Hospital and 28% of independents being reimbursed at less than their costs.
- Proposed rules will adversely affect access to care.
- Data base of HCFA is three to five years old.
- Methodology uses an arbitrary adjustment factor of 5% for hospitals.
- Composite rate methodology clearly favors independent facilities.
- Overhead allocation differential is not realistic.
- Cost information gathered on home patients is skewed.
- CAPD costs are really yet to be determined.
- The costs of CAPD are controlled by a virtual oligopoly.
- Reduction of physicians fees distort the basic concepts of ARM.
- No lead time or transition period will be allowed.
- No requirement of annual reviews.

The proposed regulations must be re-evaluated and altered significantly so that the ESRD program conforms with the intent of Congress and the needs of patients are met in an orderly fashion.

Sincerely,

Dennis Sal
Vice President
Director of Operations

/ejw

STATEMENT OF THE HOSPITAL ASSOCIATION OF NEW YORK STATE

As the representative of almost 60 hospital based renal dialysis programs, the Hospital Association of New York State protests the prospective reimbursement methodology and rates for renal dialysis services under the end stage renal disease program as published in the Federal Register on February 12, 1982.

With the exception of the Medicare program, New York State controls the revenues of all other payors including Medicaid and Blue Cross. The New York reimbursement system is prospective for both inpatient, outpatient and renal dialysis programs. The system uses costs which are two years old trended forward by an inflation factor to establish rates of payment in the rate year.

The reimbursement methodology and revenue control system leaves little room for a facility to absorb additional losses which would be imposed by the Medicare program. In 1979, 80% of 245 voluntary and public hospitals had operating losses of $267 million. Only 3% of these hospitals were able to establish an operating profit in each of the last five years (1975 to 1979). Conversely, 91% lost money in two or more of the last five years.

Outpatient renal dialysis services were provided by 56 hospitals which were members of the Hospital Association of New York State. Only five of these hospitals were able to provide the services at costs below the Federal cap of $150 ($138 + $12) for the period starting April 1, 1981. Any reduction in this payment rate only exacerbates the losses incurred by hospitals in New York State. The loss situation is further compounded by New York State's application of the Federal limit to the Medicaid program.

The Health Care Financing Administration has expressed concern about both the increasing cost and the number of patients served under the end stage renal disease program. While the number of patients from July 1, 1973 to December 31, 1979 using the Health Care Financing Administration's data has increased 286% and cost has increased 330%, the cost per patient treated has only increased 11.3% during the entire period. This percent of increase is much less than the cost of inflation alone during that same six year period. Providers have been providing efficient and cost effective delivery of dialysis services to the patients they treat.

The proposed prospective reimbursement methodology is intended to encourage more efficient and cost effective delivery of dialysis services, to promote more home dialysis and more effective delivery of home dialysis services. The Hospital Association of New York State contends that the proposed reimbursement methodology for hospital based renal dialysis services will unjustly penalize hospital based facilities for providing renal dialysis on a home basis. Hospital based renal dialysis services are already providing 23.5% of home dialysis services while the independents are providing only 10.5% of such services. If the obtainable goal for home dialysis services is approximately 30%, hospital based facilities are much closer to achieving that goal than the independent facilities. Use of the proposed prospective reimbursement methodology does not encourage the independent facilities to increase the proportion of home dialysis patients, rather through the use of the composite rate, they are unjustly enriched while the hospital based facilities are unjustly penalized.

Using "audited" data, the rates for hospital based facilities, according to the Health Care Financing Administration's data, ranged from $86 to $277. The audited costs reflect the reasonable cost for providing services to renal dialysis patients. Yet, there appears to have been no examination of why one facility provides service at $86 per patient and another facility provides services at $277 per patient with both being based on reasonable audited costs. The low cost facility was determined to be cost efficient and the high cost facility was determined to be inefficient. The Hospital Association of New York State believes that there have to be more reasons for such a cost spread. Such variables include the age of the population being served, the intensity of the services being provided, additional illnesses or diagnoses complicating the treatment process, the proportion of home dialysis treatments, State mandated regulations exceeding the Federal regulations, age of the facility, availability of group purchasing arrangements, size of the facility and the volume of treatments rendered.

Use of the median to establish rates automatically assumes that half of the providers are inefficient providers of service when, in actuality, they may not be for the type and intensity of patients being served. Such a number should serve as a screen, not as an automatic denial of cost. The figure should trigger a review mechanism to determine if the costs are appropriate and, if so, payment should be made at that rate, not at a lower rate.

The proposed reimbursement methodology is being used as a substitute for a planning mechanism and as a substitute for determining who should receive dialysis services. Health Planning should determine the need for dialysis services, the facilities to provide those services, and establish budgets for the provision of such services. The financial reimbursement mechanism should not be used as a substitute. It is inappropriate for a financing mechanism to determine the patients to be served. The use of a composite rate and emphasis on home dialysis will force the exclusion of the patient who would otherwise be served. This emphasis will force the closing of many hospital based facilities. If this is an unannounced intention of the Health Care Financing Administration, it should announce that hospital based dialysis programs are socially unacceptable.

The Hospital Association of New York State doubts that the sample of facilities used to establish the composite rate for hospital based and independent facilities is truly representative. Cost should be for the same year end period and for all facilities providing the service. Use of a small sample leaves much in question. There is a need for good solid data. Estimates should not be used. Use of anything less than a full data base is playing with the economic life of renal dialysis services in New York State.

The Health Care Financing Administration has indicated that it does not propose to trend the costs from '77, '78 and '79 used in establishing the composite rate. This procedure represents a significant departure from other methods used by the Health Care Financing Administration in establishing ceilings and rates. The Hospital Association of New York State believes that it is inappropriate not to trend costs to the rate period under a prospective methodology.

The Health Care Financing Administration has acknowledged that the allocation process does shift some costs to the renal dialysis centers. When the Medicare cost allocation process mandates that costs be allocated to the renal dialysis center, the Health Care Financing Administration cannot then select what it wants to pay for out of the mandated cost allocation statistics. Overhead costs may not be the only items that are affected by the excess allocation to areas other than inpatient.

Use of the Bureau of Labor Statistics data in construction of the wage index does not necessarily represent the personnel necessary to staff and support renal dialysis units. It is contended that the proportion of professional personnel necessary to staff renal analysis units is greater than the proportion in the wage index base.

The proposed prospective composite reimbursement methodology now transfers the cost of providing routine laboratory tests and the cost of providing aides for home dialysis patients to the facility. Such costs were not included in the base used to establish the rates. The exclusion of such costs in the base then puts another economic squeeze on the providers. The transfer of routine laboratory tests may also mean that fewer routine tests will be provided. This may have an adverse effect on the quality of care rendered to the patient. There is no review mechanism to determine the effects on quality of patient care.

The Health Care Financing Administration has acknowledged that the number of exceptions estimated to be granted under the proposed reimbursement methodology would be less than currently granted. Exceptions are needed for patient mix, case mix, intensity, age of patients served, and other issues which facilities believe are justifiable reasons for costs being in excess of the composite rate established by the Health Care Financing Administration. Exceptions should be granted on their merit, not subjected to the cost of some supposedly similar group standards established by some unspecified means. The exceptions methodology in effect precludes exceptions. Effected facilities will be unable to obtain data from other facilities to verify that they are indeed atypical.

One of the effects of the proposed prospective reimbursement methodology in New York State will be the dismantling of the national model program to assist home dialysis patients. Under the proposed regulations, the national model program would have to be duplicated by each individual facility providing renal dialysis services. Such an approach dismantles the group purchasing arrangement and adds unnecessary costs to the renal dialysis program. The composite rate will not reduce record keeping in this instance.

Use of a composite rate is not consistent with other approaches used by the Health Care Financing Administration. Movement seems to be more toward disaggregation of costs, such as a separate alternate level of care reimbursement approach. A composite rate does not pay for the cost of rendering services to Medicare patients. The composite rate represents a cost shifting to other payors of service.

The Hospital Association of New York State believes that insufficient research has been applied in the development of the proposed prospective reimbursement methodology. The data base should be extended. The spread in the range of rates should be examined to determine the reasons why such spreads exist. Different variables for groupings of cost and statistics should be examined. Standards should be tested before being implemented. The effect on patient care should be examined before regulations are implemented which may provide lower quality patient care or deny a patient access to renal dialysis treatment.

THE IOWA HOSPITAL ASSOCIATION
Suite R • 600 Fifth Ave. • Des Moines, Iowa 50309 • Phone (515) 288-1955
DONALD W. DUNN, President

April 22, 1982

COMMITTEE ON
APR 26 1982
WAYS AND MEANS

Mr. John J. Salmon
Chief Counsel
Committee on Ways and Means
Longworth House Office Building
Washington, DC 20515

Dear Mr. Salmon:

Subject: Health Care Financing Administration Proposed Rule on End Stage Renal Disease Program Prospective Reimbursement

The Iowa Hospital Association is pleased to have the opportunity to provide you information and comment regarding the HCFA proposal to implement a prospective reimbursement system for dialysis services on an outpatient basis.

The proposed rules which were published on February 12, 1982, we believe will have an unfavorable impact upon the people served by the program, remaining citizens of the state of Iowa, and the providers of services. We can state this unequivocally because health care providers in Iowa have worked together in developing an already efficient network that provides a home dialysis rate in excess of 30 percent of total dialysis procedures at the present time. This has been done on a voluntary basis, utilizing two facilities to provide home dialysis training and other satellite facilities to provide outpatient maintenance dialysis. The network now provides for 100 percent referral for the less costly home dialysis service, and as consequence the proposed financial incentives will not improve on the present performance level of home dialysis.

Implications

It is estimated that the eight IHA member providers of ESRD services will be shortchanged $2.3 million if the proposed February 12 rules are adopted. It is significant to note that the $2.3 million represents 2.3 percent of the estimated savings to the Medicare program if the regulations were adopted, but the Iowa dialysis patient population represents only one percent of the total number of dialysis patients in the United States. Therefore, the citizens of the state of Iowa would be bearing a highly disproportionate burden of the cost savings the HCFA is trying to achieve. It is further unjust that this is being levied against the responsible parties who have with the 34 percent home dialysis rate created one of the nation's successful home dialysis programs, and already have achieved the 30 to 40 percent rate HCFA considers optimal.

Furthermore, because there is not a bank of home dialysis patients from which the not-for-profit, hospital-based facilities can draw there is very little relief for the hospitals in the combined prospective payment rate. These facts are being stated to inform those concerned that there is very little room for hospitals to make decisions. The not-for-profit providers have always been audited by the Medicare intermediary and consequently the costs claimed have been been verified. To say that there is $2.3 million of fat in the Iowa satellite network would be irresponsible and would indicate that there has been no effort extended to ascertain the circumstances.

In addition to being audited by Medicare intermediaries these providers are run by governing boards who are volunteers in public service and serve without profiting from the operation of the hospital. The HCFA will be making the governing board subject to tremendous payment shortfalls These boards are already faced with reduced Medicaid payments across the board, increasingly stringent Medicare routine cost limitations, and financial pressures to maintain quality service through appropriately compensated personnel. Additional shortfalls cannot be shifted to charge based payers.

We can say, therefore, while the impact of the proposed rules will vary from hospital to hospital some of the satellite facilities in the network will be hard pressed to defend retention of their current unit in light of the escalating losses. Accessibility to patients is the real concern of the hospitals and the network. Presently, End Stage Renal Disease Network 8 has set a goal to provide dialysis services that are reasonably accessible to patients in terms of travel distance. The network felt that sixty miles one way air distance was a maximum distance patients should be required to travel for dialysis. If any facility should drop from the satellite network it will greatly increase the travel time. Since transportation cost is presently a patient responsibility his out-of-pocket costs will substantially increase. Travel time can also be a valid safety factor during times of inclement weather in Iowa such as this past winter. Also, if a patient is currently employed increased time away from the job to secure treatment will endanger the patient's employment status. Some patients, in fact, may be uprooted from their communities, where they have social and moral support, to move to a metropolitan community totally foreign to their previous environment. The trauma of relocation will certainly impact upon the tenuous balance the ESRD patient must contend with from a psychological and physical standpoint. Therefore, the remaining centers should expect to receive patients with more complex problems and higher admission rates as inpatients because of the reduced accessibility over that which was previously enjoyed.

Another ripple effect of possible closings of satellite facilities is that the space previously allocated to the centers will be incorporated back into acute and ancillary areas of the hospitals. Therefore, while HCFA may have reduced some of the outlay for the overhead they are presently requiring to be allocated to the renal centers this allocation will revert back to the hospital and manifest itself in the acute costs that must be reimbursed. The total savings, therefore, will not be the amount first expected. A net result will be that patients will have reduced accessibility and care; while the targeted savings will not be achieved.

Payment Rate

In reviewing the proposed reimbursement rate it was found that the most common rate is $119. This is for rural Iowa. The lowest cost in an Iowa facility is $144. Many larger rural facilities have even greater costs and much larger shortfalls. Moreover, the difference between Iowa metropolitan and rural rates is not that great because the highest metropolitan rate is only $128. The highest metropolitan cost projected amount is in excess of $262. The gross inequity between the cost and the proposed payment is indicative that proper studies have not been conducted and there is a heavy reliance upon data collected many years ago. Apparently, there has been no attempt to update early data for inflation that has taken place due to the increasing costs of supplies, equipment, salaries and wages. These increased costs would be evident if the HCFA would process the requests for exception to the rates for the years 1979 and 1980 that have been filed by Iowa providers.

Compounding the problem of the data lag is the element of the wage index. The wage index we believe does not accurately reflect the cost of routine care let alone the costs of the more specialized requirements of the person staffing the renal dialysis center. Iowa hospitals employ the health care professional, generally an R.N., specialized in the ESRD patient, to staff the unit. These professionals are better able to assess and assist patient in meeting their health care needs, rather than the technician that merely operates the equipment. The prospective rate simply does not reflect or adequately address the differences in labor rates paid for dialysis center staff.

Within the rate computation we believe that a five percent adjustment in the hospital rate is grossly inadequate to provide equity over the free-standing dialysis rate. The costs allocated down to the hospital-based facility are those costs incurred because of Medicare Conditions of Participation, reimbursement principles, and the multifaceted health delivery approach of the hospital; costs the free standing center is not subject to. Also we believe that if the hospital patients were presently being serviced by free-standing centers, hospital admission rates would be greater because the free-standing centers would not be able to serve the patient that the hospital outpatient center serves through the extensive hospital total health care provision.

Exception Process

The HCFA has stated that there will be very few exceptions given. This is understandable because the regulations do not define with objective standards what institutions would qualify for exceptions. For example, with a typical patient mix, the burden of demonstrating that a typical mix exists is placed upon the institution that does not have access to the patient mix records of all other providers. The institution can only blindly request an exception or expend considerable resources trying to develop the data to achieve the exception.

Likewise, the isolated essential facility exception and the educational costs exception are only written in general terms providing factors to be looked at but giving no specific standards for objective measurement. This section like the section which provides for a minimal difference between free-standing, independent, and hospital-based dialysis centers appears to provide a token response to Congress for an exception process and is entirely subjective in nature. Moreover, to state that the exception process can be appealed to the Provider Reimbursement Review Board which itself is subject to review by the Administrator, is to again prevent the hospital from having a speedy and equitable resolution to the issue.

Summation

In summary, members of the Iowa Hospital Association on their own encouraged, over the last few years, home dialysis. These forerunners have reduced their present volumes by encouraging home dialysis and supporting the satellite network. Reducing their volume thereby increased their per unit costs. There is no bank of patients for these satellite hospitals to place on home dialysis and regain some of the loss they incur on an outpatient dialysis unit. Because the patients that are eligible for home dialysis are already on that modality, the patients that are presently being treated on an outpatient basis are by definition more in need of professional health care providers.

Accordingly, the hospitals are operating as efficiently as possible now. Anything said to the contrary ignores the facts and the issue. The Congress intended that efficient providers would not be penalized. It can be readily demonstrated that the proposed payment system will heavily penalize the hospitals that have already been in a home dialysis program. Therefore, the HCFA should withdraw the proposed rules at this time and then do comprehensive studies of all regions of the country, not just the Eastern, to determine the actual costs of hospitals, the case mix and type of patient hospitals serve, and the efficiencies of the various end stage renal disease networks.

Thank you for giving us the opportunity to provide comment on these proposed rules.

Sincerely,

Donald W. Dunn

Donald W. Dunn
President

DWD/DH:bja

Kidney Center of Delaware County Ltd.,
Woodlyn, Pa., April 21, 1982.

Re: NPRM, Federal Register, Vol. 47, No. 30, Feb. 12, 1982.

Mr. Richard B. Lowe III,
Counsel, Oversight Subcommittee, Committee on Ways and Means, Longworth Office Building, Washington, D.C.

Dear Mr. Lowe: Confirming our telephone conversation of April 16, 1982, I'm enclosing copies of our response to the Notice of Proposed Rule Making published in the Federal Register, Vol. 47, No. 30, dated Friday, February 12, 1982.

With the exception of the letterhead and signature, the comments and recommendations from the Kidney Center of Delaware County and the Kidney Center of Chester County are alike; however, the comments and suggestions from Clinical Renal Associates, Ltd. are somewhat different. In either case, the letters express our views that were made known to Dr. Davis and delivered to HCFA's Baltimore location on April 12, 1982.

We feel it is important that your committee also have benefit of these views while conducting your hearings and deliberations on this serious matter.

Please contact me if you have any questions concerning our response to the NPRM.

Very truly yours,

A. Leo Coyle,
Chief Executive Officer.

Enclosures.

Kidney Center of Delaware County Ltd.,
Woodlyn, Pa., April 9, 1982.

Re: BPP-126-P.

Carolyne K. Davis, Ph.D., R.N.,
Administrator, Health Care Financing Administration, Post Office Box 17073, Baltimore, Md.

Dear Dr. Davis: Our review and analyses of the NPRM as stated in the Federal Register, Vol. 47, No. 30, dated Friday, February 12, 1982, compels us to make the following comments and recommendations:

I. COMMENTS

A. *Inadequate information.*—Without providing full details of the rate-setting methodologies that HCFA intends to use to implement their proposed regulations (page 6558, paragraph II,A.) and without providing the most recent Wage Index for Urban Areas that will actually be used by HCFA in determining rates for freestanding facilities (page 6581, appendix II, paragraph B.) we are unable to determine the financial impact these proposed rules will have upon our facility if implemented. If we are indeed forced to deal in averages, $128 (page 6566, Paragraph 1.3) versus the current screen of $138, then we are looking at a 7.2 percent reduction in revenue per incenter dialysis offset by the added revenue of receiving $128 per dialysis performed at home less the cost of supporting the home patient. We're not certain what that will mean financially, but we have a strong feeling that (based on our mix of incenter and home patients) we stand to lose revenue. Your uninformed intermediaries are no better off than we are and HCFA's contention that a rate reduction is not expected to affect the quality of care (page 6577, col. 3) amounts to rhetoric for patient consumption.

B. *Methodology or mythology?*—The data base used by HCFA in determining the prospective rate per dialysis was taken from a "stratified" sample of 105 facilities, 38 of which related to freestanding facilities (page 6562, paragraph III.D.). The information provided in this NPRM fails to engender confidence in the validity of the sample selected. For example, freestanding facilities with reported costs in excess of $500,000 were excluded from the sample (page 6562, paragraph III.D.).

There is no information about the 38 freestanding facilities selected for audit concerning reuse of dialyzers, composition of staff (RN's/Techs), staff to patient ratios or location of the facility. All of these factors and more have great impact on costs and therefore the results of an audit of a nonrepresentative group of facilities give rise to the prospect of a loaded vice valid sample.

Additionally, it is our understanding that these audits were limited in scope and conducted under severe time constraints which precluded, in many instances, the opportunity for facilities to fully discuss and justify reported costs, nor was there much opportunity to challenge arbitrary audit adjustments made by HCFA. Such unilateral adjustments and Medicare accounting assertions include, but are not limited to, such disallowances as return on equity capital of proprietary providers and a limit of $32,000 per year compensation for medical directors and administrators. These audit adjustments resulted in reducing reported costs of freestanding facilities by about 15 percent as compared with about a 3 percent reduction for hospital-based facilities. Freestanding facilities have been plagued by HCFA since the inception of the ESRD program by applying the most restrictive rules of both the provider and non-provider regulations. Effectively, freestanding facilities have experienced the worst of both worlds.

HCFA's policy statement of 1974 clearly stated their goal of having all hospital performed outpatient dialyses switched to home dialyses wherever possible and if not at home, then in a freestanding facility. That policy gave rise to and encouraged proprietary freestanding facilities to be established and provide outpatient treatments within a pre-determined screen. With rare exception, freestanding facilities have lived within this screen since 1974, and even if HCFA now thinks the screen was initially set too high, one finds it hard to imagine that, some eight years later, anyone would now consider it excessive. The imposition of a limit of $32,000 per year compensation for medical directors and administrators is certainly a landmark decision on the part of HCFA and sets the upper limit of what HCFA considers reasonable.

We consider such a limit as ingenuine and laughable. If we have missed the point and HCFA is serious in establishing such a limit then we have great concern for the continued success of the ESRD program under its present leadership. Disallowing a return on equity has and continues to be unacceptable and obviously needs court testing to be resolved.

The proposed prospective reimbursement rate was determined from costs reported for various periods from 1976 through 1979 with no adjustments for inflationary indices. HCFA's failure to adjust for inflation and use of the median in their calculations renders the proposed prospective reimbursement rate arbitrary and inaccurate to the point where it becomes obvious that the formula was contrived to produce a pre-determined reduction in program costs. When it comes to increased program costs, it is not the freestanding facility's cost per treatment that accounts for steep rises in the cost of the ESRD program, but rather the dramatic increase in the number of patients suffering with ESRD. HCFA's persistence in applying provider rules to freestanding facility nonproviders is tantamount to blaming the harbor when the ship (HCFA) misses the port.

C. *Proposed independent facility rate.*—Any new proposal for rate setting which excludes a specific inflation factor and annual adjustments is unacceptable, particularly after eight years without such a provision. We disagree with HCFA's opinion that "the new prospective rate structure offers substantial opportunity for additional profit . . ." (page 6565, paragraph H.). Many freestanding facilities do not provide home training, support few or no home patients and to say or imply that the incentive of paying facilities for dialyses performed at home will make a patient well enough to dialyze at home or create a trained helper or physical home conditions suitable for safe home dialysis if such conditions do not already exist is utter nonsense. Even if such an incentive could make it possible to significantly increase the number of patients dialyzing at home (and we don't think it could), there is little confidence that such an incentive would last one day longer than reaching the goal of having 30 to 40 percent of all ESRD patients dialyzing at home (page 6577, col. 3). HCFA's use of 10.5 percent for calculating home dialysis rates in the freestanding facility and 23.5 percent for hospital based facilities is inconsistent, unjustified and discriminates against the independent facility.

D. *New cost reporting forms.*—A new cost reporting form (page 6580 and 6581, paragraph E) developed by HCFA under current regulations, although not part of current regulations, has been retroactively and arbitrarily implemented and applied to independent freestanding facilities for cost reporting periods ending on or after September 30, 1981. Although HCFA claims to have made the new cost reporting from (HCFA 265) available for comment, they fail to state who had the opportunity to review and comment—we certainly did not. Our first official notification appeared in the NPRM dated February 12, 1982. Our next official notification arrived on April 1, 1982 from our intermediary. It would be interesting to know who commented, what the comments were and what impact, if any, they had on HCFA. This action appears to be a classic case of imposing provider (hospital) regulations on non-provider independent, freestanding facilities. In total disregard for national goals of reducing paperwork and lessening oppressing regulations on private enterprise, HCFA summarily dismisses the significantly increased workload placed on independent freestanding facilities with the statement that "these requirements will place little additional recordkeeping burden on independent dialysis facilities." Our review of the new ten page cost report (HCFA-265) and its twenty-nine page instruction discloses that nothing could be further from the truth. This new cost reporting system will require a complete revamping of our accounting system in order to satisfy HCFA's demands for cost information broken down, reclassified and adjusted in an excessive number of ways. There is no telling how much additional effort will be expended to redo cost reports already filed on the SSA 9734 by freestanding facilities during the first quarter of 1982 and before appropriate notification. The problem is further compounded by a year of accounting and statistical records that have been maintained in sufficient detail to support the completion of the SSA 9734 but are hardly adequate, without a significant effort, to support the retroactive requirements of completing the new (HCFA-265). We strongly object to the implementation of the new cost reporting system for independent freestanding facilities without an adequate review, comment and adjustment period.

II. RECOMMENDATIONS

Although we agree with the Congressional mandate to HCFA to reduce program expenditures by 100 million dollars, we cannot agree with HCFA's NPRM to accomplish these reductions. In the spirit of cooperation we propose the following alternatives to the proposed NPRM:

A. Consistent reorganization within HCFA over the past several years has resulted in the loss of corporate knowledge, stability, experience and morale within HCFA. We strongly suggest that HCFA establish an office or group of persons who are more experienced in ESRD operations, current in the state of the art and represetative of the ESRD community at large. The group would be responsible for policy and operational decisions and be given authority commensurate with their responsibilities. An offer of $32,000 per year compensation would not attract the persons or the experience we are suggesting). Forthcoming proposed regulations from such a group would be more rational than now exist and would represent the combined thinking of all participants in the ESRD program and evidence the wide participation and cooperation so necessary for general acceptance and success.

B. The proposed rules should be withdrawn and revised after an accurate cost data base is developed and analyzed—not contrived. We recommend soliciting the services of one of the top five public accounting firms in order to achieve complete objectivity in determining actual costs. We also recommend that HCFA keep an open mind in determining allowable cost for independent freestanding facilities and not blindly apply the restrictive medicare regulations to non-providers. If mutually agreeable ground rules could be established among HCFA, facilities and the public accounting firm selected, the data base established by their audit of costs would be mutually acceptable and obviate the need for cumbersome annual cost reports from facilities, the need for intermediaries to audit (desk or otherwise) facilities, the need for Regional Offices to check on intermediaries and the need for HCFA to check on all of the above. Except for facilities, none of the organizations mentioned provide ESRD patient care. The reduction of effort within the described governmental strata would surely result in significant cost reduction within the ESRD program and solve the problem of HCFA's demonstrated inability to generate accurate cost and statistical data.

C. Considering eliminating all but the most deserving exceptions to the screen (hospital based and freestanding alike—which has not been the case to date). Implementing this suggestion has the potential of saving 50 to 60 million dollars each year.

D. Eliminate additional reimbursement for routine laboratory tests, thereby considering the reimbursement rate to encompass these additional expenses.

E. If previous suggestions fail to achieve required reductions in program costs, then we would recommend that the remaining reductions be accomplished through an across-the-board percentage basis reduction for the hospital based facility, the independent freestanding facility and the physician's monthly reimbursement.

Very truly yours,

A. Leo Covitz,
CIA, Chief Executive Officer.

A letter identical to the above was received and signed by: Hardy L. Sorkin, M.D., Co-Medical Director, Kidney Center of Chester County, Ltd., Downingtown, Pa.

Clinical Renal Associates, Ltd.,
Chester, Pa. April 12, 1982.

Re: BPP-126-P.

Carolyne K. Davis, Ph.D., R.N.,
Administrator, Health Care Financing Administration, Post Office Box 17073, Baltimore, Md.

Dear Dr. Davis: After reviewing the NPRM in the Federal Register, Fol. 47, No. 30, dated Friday, February 12, 1982, we feel compelled to make the following comments and recommendations concerning HCFA's proposed method of physician reimbursement:

I. COMMENTS

A. *Methodology.*—The proposed method of computing physician reimbursement by means of a monthly capitation payment is faulty and inconsistant with the alternative method of reimbursement (ARM) as established in 1974. The existing ARM system of reimbursement uses factors of 14 and 20 times the rate for the physician's follow-up visit to compute the monthly reimbursement rate for home patients and in center patients respectively. The resultant rate effectively becomes a per diem paid monthly for the types of services furnished by physicians in the ESRD program including their expertise, specific procedures, cognitive skills and oncall responsibilities. In contrast, the proposed system uses a factor of 12.4 (HCFA's determination of the average number of patient treatments per month) times the brief office visit charge plus one intermediate follow-up office visit charge to arrive at a base sum. The base sum is then weighted for in center patients by multiplying by .83 and for home patients by .17 (83 percent and 17 percent being the national average of patient dialyzing in facility and home respectively). The calculation for weighting for home patient then goes on to multiply the result of the (base sum x .17) by .7 which HCFA says is representative of the 10:7 (or 20:14) facility/home physician treatment capability ratio used under the current ARM. It becomes obvious that the second reduction by multiplying by .7 to adjust for the home patient population is not justified and is illogical and only serves to reduce the monthly capitation payment. It appears as though HCFA made a formula out of whole cloth to arrive at a predetermined amount to be saved rather than an orderly rational approach.

B. *Results of the proposed calculation.*—The results of our calculation based on the proposed regulation (which could not be confirmed by our intermediary as being correct or incorrect) indicates an overall reduction of 32 percent of revenue with no alternative of reducing expense without reducing physician care of the ESRD patient. Reducing physician care has a definite negative effect on quality of care and is unacceptable, and HCFA's opinion that reducing rates is not expected to affect the quality of physicians' care to ESRD patients (page 6577, Col. 3) is sheer folly.

Our calculation shows that the proposed capitation rate is 33.9 percent lower than the existing in-facility rate and 5.5 percent lower than the existing home dialysis rate. When HCFA's proposed monthly capitation rate is lower in either setting, then we strongly disagree with HCFA's position that the proposed physicians' monthly composite capitation rate is "federally neutral" (page 6560, paragraph F). Federally devastating is a better description.

C. *Proposed physician rate setting factors and frequency.*—Any proposal for physician rate setting which does not provide for a generally accepted index of change in the cost of living and for annual adjustments is an has been completely unacceptable. Since 1974, whith the exception of one adjustment in 1978, HCFA has not adjusted the nephrologists' monthly rate for treating ESRD patients. Physicians practicing in other specialties and subspecialties have not experienced this disregard for regulations and statutory authority in medicare reimbursement. HCFA's lack of justification for discriminating against the nephrologist treating ESRD patients in this regard is deplorable and demands prompt rectification.

D. *Incentive versus disincentive.*—Acknowledging HCFA's positions, without agreeing with it, that physician reimbursement rates may have initially been set too high, certainly (some eight years later and with only one minor increase in 1978) one could not consider them excessive now. Establishing a monthly composite capitation rate that provides the same rate regardless of treatment made and setting has certainly removed the physicians' disincentive for sending patients home to dialyze; however, when the proposed monthly rate is below both current ARM rates then all that is left is disincentive in any case. While it is always the physicians' responsibility to recommend the best modality and setting for his patient (as the physician sees it) the final decision is always that of the patient. Placing financial incentives (reimbursing facilities for dialysis done at home) will never make the patient well enough to dialyze at home or create helpers or physical home conditions suitable for safe home dialysis, if such conditions do not already exist. With rare exception, offering such a financial "incentive" is an affront to the integrity of nephrologists.

II. RECOMMENDATIONS

While we are aware of the congressional mandate to HCFA to reduce program expenditures by 100 million dollars, we are not in agreement with HCFA's proposed regulations to implement such savings. Accordingly we propose the following:

A. HCFA should consider establishing an office or group of persons who are more experienced in ESRD operations and who are representative of the ESRD community at large. This group would be responsible for Policy and Operational decisions and be given the authority to ge along with their responsibilities. Forthcoming proposed regulations from such a group would be more rational than now exists and would provide HCFA with staff stability as opposed to the consistent loss of corporate knowledge through continuous reorganizations.

B. The proposed rates should be withdrawn or at least shelved until an accurate data base is developed (excluding the use of the median), analyzed, and not contrived.

C. Consider eliminating all but the most deserving exceptions to the screen (hospital based and freestanding alike). Such exception eliminations have the potential for saving 50 to 60 million dollars each year.

D. Consider eliminating additional reimbursement for routine laboratory tests, thereby considering the reimbursement rate to encompass these additionial expenses.

E. If previous recommendations fail to achieve the required reductions in program costs then we would recommend that the remaining reductions be achieved through an across the board percentage-basis reduction for the hospital based facility, the freestanding facility and the physicians' monthly reimbursement.

Sincerely yours,

JAMES E. CLARK, M.D.

STATEMENT OF DR. NABIL W. MOUKHEIBIR, KINGSPORT DIALYSIS CENTER FOR HIGH BLOOD PRESSURE AND KIDNEY DISEASES, KINGSPORT, TENN., TRANSMITTED TO THE SUBCOMMITTEE BY CONGRESSMAN JAMES H. QUILLEN

SUBJECT: The proposed new rates of reimbursement of chronic hemodialysis.

A. OBJECTIVE:

To cut down on the cost of dialysis in patients with End Stage Renal Disease (E.S.R.D.), with minimal detrimental consequences on the dialysis system.

B. PRELIMINARY:

We are all aware of the current state of the economy and we certainly all need to cut down on our expenses.

It is also well known that in a economical system, the different components are held together in an interdependent relationship so that when a factor is being modified, there is an automatic readjustment of all other components in order to reach a new state of equilibrium. The latter, sometimes, is a very undesirable state much worse than the one we desire to change.

Unfortunately we perceive the recent proposals to cut down on the dialysis reimbursement, to be one of those solutions that will aggravate the current situation and make it more expensive to carry the ESRD program.

In order to achieve a successful solution to our objective we ought to answer the following fundamental questions:

1. Do we wish to provide survival to patients afflicted with End Stage Renal Disease?
2. Do we wish to apply "socialized medicine" system in the United States?
3. Do we wish to live in a "free enterprise" soceity?

If we answer affirmatively to questions 1 and 3 and negatively to question 2, then we have by force of logic, to realize how wrong and self defeating is the proposed solution described in the federal register of February 12, 1982.

This latter proposition has the appearances of answering "no" to the 2nd. question and "yes" to the others, but is trying to solve the problem as if their answers were just the opposite, and that is paradoxical.

C. DEVELOPMENT:

In the particular case of the delivery of hemodialysis, the proposed regulations, as described in the federal register of, February 12, 1982, concentrate specifically on cutting the reimbursement of the dialysis centers from the current figure of $138.00 to $117.00, a cut of 15%.

C. DEVELOPMENT: Con't.

The doctor's fees are being cut from $193.40 per month, to $179.51, a decrease of 8.7%.

This initial figure of $138.00 has been the same since 1973, the year the ESRD program started, until the present moment.

During that same period the cost of all dialysis related equipment has been increasing. In other words the Renal Physicians providing dialysis service have been going on an ever narrowing margin of benefits.

At this time however, we are facing the real possibility of closing down because of our inability to sustain losses.

This is a very illustrative example of how one single particular aspect of a larger problem has been tackled in a "quick fix" fashion with total disregard to the whole, and the rest, of the health providing system.

For example: While it has concentrated on the reimbursement of the dialysis cost to the renal physician, it did not take into consideration the other components of the system of the medical care delivery, of which dialysis is only a small part.

1. It did not consider the manfacturers of dialysis related equipment, both disposable and nondisposable.

2. It did not consider the continuous increase in the price of biological and nonbiological injectables.

3. It did not take into consideration the coinsurance which has arbitrarialy been held responsible for only 20% of the total bill.

4. It did not take into consideration the disruption of the life of the patient who has to travel more, to a farther center, in case his nearer center has been obliged to close down.

5. It did not consider the consequences of such a disruption with its attendant increased morbidity and hospitalization.

6. It did not consider other important economical factors due to travel to farther places in terms of gas, car expenses and the cost of ancillary human aids.

7. It did not consider the important obligatory drop in the quality of care that is an inevitable consequence of reduced reimbursement.

D. PROPOSITION:

Because of all of the aforesaid we would like to propose a totally new system of reimbursement that we believe will take care of both, the interest of the patient and that of the general economy of the country.

1. The active participation of the physician in sharing the burden of restricting expenses would be manifested by accepting the old reimbursement rate.

2. The patients should be subdivided into two groups according to their financial abilities:

   The financially disabled group shall be paid completely by the government.

   The financially able group should be paid 50% by the government and 50% by private insurances.

   The methodology of separating the population into less able and more able financially should be the same as that used for other criteria of government assistance.

3. A new system of insurance must be created that will enable the insurance companies to support 50% of the bill.

4. The hemodialysis related industries should be ask to cooperate in this general solution of the problem by bringing down their prices to more appropriate levels.

   In this way the government will have a smaller bill to underwrite, the private sector will share in the burden of the suitation just like the renal physicians are willing to do.

We preceive such a pluralistic approach to the problem of dialysis delivery, to be more beneficial to all parties concerned.

We do not pretend that the above described solution is a unique solution but rather a prototype to be followed.

Otherwise, we foresee an irrevocable slide toward more and more government control which, in itself, becomes a very costly enterprise and will add up simply to a socialized type of medical care delivery in the United States.

Nabil W. Moukheibir, M.D.

Michael Reese Hospital and Medical Center
434 East 26th Street
Chicago, Illinois 60616
(312) 791-2967

COMMITTEE ON
APR 26 1982
WAYS AND MEANS

April 19, 1982

Representative Dan Rostenkowski
Rayburn House Office Bldg. Room 2111
Washington, D.C. 20515

RE: BPP-126P Prospective Reimbursement for Renal Dialysis Services,
Federal Register Vol. 47, #30, Pages 6556/6581, Proposed Rules.

Dear Representative Rostenkowski:

Enclosed are our comments pertaining to Health Care Financing Administration's (HCFA) proposed prospective reimbursement for renal dialysis services. Our comments only touch on what we feel to be some of the major draw backs and misrepresentations of the proposed rules.

The following is a summarization of the major points of our reply:

1. There is a total lack of any analysis by HCFA as to the effect of these proposed rules on the level of quality care rendered to recipients.

2. The major force causing the 'high and steadily rising costs' is not due to extraordinary increases in facility costs per beneficiary but rather the explosive increase in the numbers of beneficiaries receiving renal dialysis benefits.

3. The rate setting methodology in reality is a retrospective system which does not set two distinct and independent rates as per Congress's instructions but rather creates an averaging of the hospital-based facility's rate and independent facility's rate.

4. The exception request system is far too restrictive and cumbersome to allow timely relief to facilities for inadequate rates.

5. There was no attempt on HCFA's part to determine an appropriate, adequate, or reasonable reimbursement rate for its prospective system, let alone establish a mechanism to determine what the full financial requirements of an efficient and cost effective facility are.

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We at Michael Reese Hospital and Medical Center make these comments as supporter of the State of Illinois' prospective rate setting program and from the point of view of welcoming the real development of innovative and adequate prospective reimbursement methodologies as viable alternates to the inadequacies of retrospective reimbursement.

Any inquiries to this response should be addressed to Jacob R. Lewis, Jr., Director, Reimbursement and Cost Control, (312) 791-2114.

Sincerely,

Jacob R. Lewis, Jr.
Director
Reimbursement & Cost Control

JRL:eas
Enclosure

Michael Reese Hospital and Medical Center
434 East 26th Street
Chicago, Illinois 60616
(312) 791-2967

April 12, 1982

Carolyne K. Davis
Administrator
Department of Health and Human Services
Health Care Financing Administration
P.O. Box 17073
Baltimore, Maryland 21235

RE: BPP-126P Prospective Reimbursement for Dialysis Services, Federal Register Vol. 47, #30 pages 6556-6581, Proposed Rules.

Dear Carolyne Davis:

We at Michael Reese Hospital and Medical Center (MRHMC) as supporters of the State of Illinois' Prospective Rate Setting Program applaud HCFA's and Congress's attempt to establish a prospective system of reimbursement for the Renal Dialysis portion of Medicare's End-Stage Renal Dialysis (ESRD) program. We, though, must take exception to the manner in which HCFA's program was developed, the material utilized to determine HCFA's rates, the adequacy of HCFA's program, and the prospectiveness of HCFA's Rates.

Quality Care

First and most important in our minds is the overall effect that this new approach to financing is going to have on the quality of care rendered Renal Dialysis patients. Especially, in relation to what we feel is an inadequate system of rates. Our concern stems from the total lack of consideration given this subject in the proposed rules. One can only surmise from the statement on page 6561 of the Federal Register, Vol.47, #30 (FR) that "There are no uniform standards for the numbers and qualifications of personnel, or for staff-to-patient ratios, and the dialysis service seems to vary in intensity of care depending on the patient's health status.", that HCFA assumes the quality of care to be equal at every facility audited and that the vast range of differences in the costs of these facilities is totally due to the efficiencies of each facility, including the mix factor of home and in-facility patients. Only that assumption would allow the rational conclusion that the median cost of these facilities be utilized in establishing a prospective reimbursement rate. We question the validity and reasonableness of an assumption that would simplistically state that facilities rendering care at $86 per treatment were rendering the same level of quality care as a facility rendering care at $277 per treatment.

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HCFA's assumption is indicating that facilities whose costs are under the median are efficient and those whose costs are over the median are inefficient. How can HCFA make such an assumption when in fact no attempt has been made by HCFA to define a standard by which to measure a facility's level of quality care against. By ignoring the level of quality of care issue we as a facility do not know what product HCFA is purchasing nor does HCFA as the purchaser know what product the recipients are receiving. Only by defining the minimum specifications required for a treatment can the proper reimbursable amount for renal dialysis be determined and the efficiency of a facility rendering renal dialysis treatments be measured.

We would not like to see the renal dialysis facilities lower their quality care as one of their avenues to becoming more efficient to meet HCFA's specified reimbursement rate only to find at a later date that the required standard minimum level of care requires a higher level of reimbursement than the median allowed.

Prospective Reimbursement Concept

Let us reiterate that we were excited to hear that HCFA was to develop an alternative to the retrospective cost reimbursement methodology. HCFA has an opportunity to create an innovative, efficient oriented reimbursement system for renal diaylsis. The reimbursement methodology proposed in the FR under the disguise of "Prospective Reimbursement" is in reality Retrospective Cost Reimbursement reimbursed in the future. We see no attempt on HCFA's part to determine an appropriate, adequate, or reasonable reimbursement rate for its prospective system, let alone established a mechanism to determine what the full financial requirements of an efficient and cost effective facility are. Rather HCFA chose to take a small 12-13% sample of hospital based and independent facilities, determine the median cost per treatment of each of these two groups and utilized this cost per treatment, without an inflationary factor, which is based on data that will have an average age of 43.6 months on 05/03/82 to establish the "Prospective Rate". In other words, HCFA took a piece of data over 3½ years old based on a retrospective cost reimbursement methodology and made it the "Prospective Rate" without trending it forward for any type of inflationary figure. How can HCFA justify this as a prospective reimbursement system?

"High and Steadily Rising Costs"

On page 6566 section I.B. of the FR HCFA admits that the present program "has been generally successful in protecting renal disease patients against the catastrophic costs of needed care." HCFA goes on to state that this effectiveness is being undermined by the "high and steadily rising costs." The implication of these statements is that the renal dialysis facilities, as a group of providers, have allowed costs to run rampant and have made no attempts to be cost effective or productive. We would like to describe a vastly different scenairo of costs. On Table 1, Appendix A is the layout of the numbers and beneficiaries by year, the corresponding benefit payments, and a calculation of the benefit payments per beneficiary. These figures were all derived from the FR. Table 2.

Appendix A shows the total percent increases (decreases) in the number of beneficiaries, benefit payments and payments per beneficiary between the periods. Table 3, Appendix A shows the above figures on a per year basis.

Appendix A indicates that while the number of beneficiaries increase by 345% between 1974 and 1982, the benefit payments per beneficiary only increase a total of 3.5% or approximately .4% per year. In fact, in the period between 1979 and 1982 the number of beneficiaries appears to be stabilizing at an average of 5% increase per year with a corresponding average decrease in benefit payments per beneficiary of over 2.3%.

The data on Appendix A gives a totally different view of the Renal Dialysis Cost situation. The major problem with "High and Steadily Rising Costs" is not caused by the renal dialysis facilities, rather the facilities have actually decreased their costs per beneficiary by 7% over the last three years and in the prior five years averaged increases of only 2% per year. The problem appears to be the dramatic increase in the number of beneficiaries over the eight year period of 345%. This explosive growth has created in the initial five years of the program a massive expansion of facilities approved by HCFA from approximately 400 in 1974 treating an average of 27-28 beneficiary to 975 facilities in 1979 treating an average of 43-44 beneficiares. This 43-44 beneficiary average per facility appears to hold true for the last three years. The start up costs and initial inefficiencies associated with this explosive growth of facilities, i.e., organization costs, initial inventories and non-depreciable equipment, higher fixed costs per beneficiary, etc., will have had a substantial impact on creating the minor 2% increase in costs per beneficiary per year. The fact is that Appendix A shows that since the majority of potential renal dialysis beneficiaries have been identified the growth in the beneficiary population has slowed down to an average of 5% per year for the last three years and that during this period renal dialysis facilities decreased their costs per beneficiary by an average over 2% per year while inflation increased by double digits.

Based on the above analysis we would not categorize the renal dialysis facilities with causing 'High and Steadily Rising Costs'. We find it strange that no analysis of this type was presented by HCFA nor any mention of the effects caused by the increase in the numbers of beneficiaries. Why was this very important part of the 'high and steadily rising costs' ignored?

Computation Of The Prospective Rate

We have identified in the computation of the prospective rate for hospital based facilities the following items that we take exception to:

1. Age Of Median Costs: We feel that utilizing the median of over 3½ years old average data and projecting it to the future as the reimbursement basis without adjustment is a very inaccurate methodology for determining the 'prospective rates' of that model. We further suggest that his new methodology incorporate the full financial requirements of an efficient, effective facility with allowances for variances in uncontrollable fixed costs.

006.FF.3

2. All Facilities Median Costs: If the intent of the prospective rate setting is to determine separate rates for hospital-based and independent facilities why are we utilizing an all facility median to determine the rate? Obviously, this one factor understates hospital-based rate by $7.70. Since median data has been chosen by type of facility and Congress has indicated that a two rate system will be developed, we feel that to properly compute the hospital-based prospective rate under the proposed methodology that the hospital-based median data be utilized. This would also take care of any overhead differentials between hospital-based and independents and still correct the understated hospital-based rate by $6.01.

3. 1.05% Factor: How was the 1.05% factor to determine hospital-based rate chosen? Why not 1.02% or 1.20%? HCFA appears to have little confidence in its own methodology for setting hospital-based faciliity rates. Yet HCFA is setting a series of rates that may terminate the business of a number of hospital-based facilities due to the rate being set erroneously low by this methodology. We find this totally unacceptable from the patient care point of view.

Exceptions:

We feel that the exception request is too restrictive, cumbersome, and only allows for prospective annual charges. Why is it that a facility could only have higher costs due to an atypical patient mix, natural disaster, or as a sole community provider? For a facility to prove that it has an atypical patient mix, which is the only avenue open to a large city facility, will cost that facility a great deal in money and manpower doing surveys of not only other local facilities but also facilities in other large cities. The rates being set do not allow for these costs. There is no mention in the proposed rules as to how HCFA plans to eliminate the unacceptable lengthy time period experienced to receive a decision under the previous exception process, especially since we expect the number of facilities requesting exceptions to increase.

Summary:

We would like to take this space to summarize what we feel are major draw backs to the hospital-based facilities of HCFA's proposed rules establishing prospective reimbursement for outpatient renal diaylsis services and our findings:

1. The lack of any address by HCFA to the issue of quality of care as to: the expectations of an acceptable level of care, a definition of quality of care, or even, the effect of cost cutting by facilities on the present level of quality care.
2. The major force causing the 'high and steadily rising costs' is not due to extraordinary increases in facility costs per beneficiary but rather the explosive increase in the numbers of beneficiaries receiving renal dialysis benefits.

3. The rate setting methodology in reality is simply a system that takes very old retrospective data and places that data without adjustment in the future. The methodology was to establish two distinct rates, one for hospital based and one for independent facilities, to identify the differences in operating modes, but, in reality is a methodology which utilizes averages from all facilities to set the two rates. The methodology and data appear to be suspect as to its accuracy even by HCFA as revealed by HCFA's need to include a % factor in developing the hospital-based rate.

4. We feel that the exception request system is too restrictive and cumbersome to allow timely relief for what we expect to be a greater number of facilities requesting exceptions than in the past.

Again, these comments are made from a point of view that welcomes the development of innovative prospective reimbursement methodologies as alternatives to the inadequate retrospective cost reimbursement. We unfortunately find that the approach utilized in HCFA's proposed rules is in reality a rehashing of the inadequates of retrospective reimbursement.

Any inquiries to this response should be addressed to Jacob R. Lewis, Jr., Director, Reimbursement and Cost Control. (312) 791-2114.

Sincerely,

Jacob R. Lewis, Jr.
Director
Reimbursement & Cost Control

JRL:eas
Attachment

006.FF.5

APPENDIX A

Table 1: Beneficiaries And Benfit Payments

Year	# Of Beneficiaries	Total Benefits Payments	Payments Per Beneficiary
1974	11,000	$ 229,000,000	$20,818
1979	42,500	985,000,000	23,176
1982	49,000	1,056,000,000	21,551

Table 2: % Increase In Beneficiaries And Benefit Payments

Period	Increases In Beneficiaries	Increases In Benefit Payments	Increases In Pymts Per Beneficiary
1974 to 1979	286.36%	330.13%	11.33%
1974 to 1982	345.45%	361.14%	3.52%
1979 to 1982	15.29%	7.21%	(7.01%)

Table 3: % Increases In Beneficiaries And Benefit Payments

Period	Years In Period	% Incr. In Beneficiary/ Year	% Incr. In Cost/ Year	% Incr. In Pymts Beneficiary/ Year
1974 to 1979	5	57.27	66.03%	2.27
1974 to 1982	8	43.18	45.14%	.44
1979 to 1982	3	5.10	2.40%	(2.34)

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COMMITTEE ON
RECEIVED
APR 30 1982
WAYS AND MEANS

April 20, 1982

Mr. John Salmon
Chief Counsel
Committee on Ways and Means
1102 Longworth House Building
Washington, D.C. 20515

RE: Part IV
Department of Health and Human Services
End-Stage Renal Disease Program;
Prospective Reimbursement for
Dialysis Services: Federal Register
Friday, February 12, 1982

Dear Mr. Salmon:

The Pediatric Hemodialysis Program at the University of Minnesota began approximately 12 years ago. At that time the technologies available for the hemodialysis of small children were essentially nonexistant. We developed, without major changes in dialysis machine specifications, the design of pediatric vascular access procedures and shunt materials, dialyzers and lines adapted to the special needs of children, weighing techniques, and protocols for safe and efficient treatment. As a result of our experience and publications in these areas, we developed a wide referral base for children with acute and chronic renal failure. In tandem the surgical interest in transplantation of small children grew at this institution, and thus we became among the foremost centers of its kind. In fact, with this combined team approach to pediatric renal failure we developed the world's largest pediatric transplant service, with special interest in children five years of age or younger.

Stated another way, we have never considered long-term dialysis to be optimal treatment for children. Problems of poor growth, major negative psychological impact, family stress, expense and technical (especially vascular access) difficulties are inevitable with chronic dialysis in children. Thus, we have seen and continue to see our primary patient care goals in pediatric dialysis to be those of support of infants and children in acute renal failure and preparation of children for transplantation.

At present (1981-82 statistics) 60 percent of pediatric dialysis treatments require 1:1 nursing support and 1:2 to 1:3 technician support. The remainder of our pediatric patients, with few exceptions, require 1:2 nursing care. We anticipate, based on present patient referral trends that this proportion of staff intensive dialysis is likely to continue to increase. The increased cost of pediatric dialysis at our hospital is almost entirely explained by these staffing imperitives. The remainder is due to increased laboratory costs (vide infra).

It is critical that we emphasize that the University of Minnesota Pediatric Renal Failure Program is a national resource for the care of children with end-stage renal failure. In a state with approximately 2% of the population of the USA we perform approximately 25% of the transplants in children under 5 years of age. Thus, more than 80% of the young children treated at this facility come from outside the state of Minnesota. In addition, 61% of the children between ages 6 to 10 that receive kidney transplantation at the University of Minnesota come from out of state (a map of patient referrals up to 1979 is enclosed, Figure 1).

These data reflect several important realities. Firstly, as already mentioned, we are a facility whose philosophy it is to perform renal transplantation, usually from living-related donors, in all children in end-stage renal failure. The strategy is to perform dialysis in preparation for and in support of transplantation. Thus, the average duration of dialysis in preparation for transplantation of our pediatric patients is less than 6 weeks. Although transplantation is the preferred treatment for chronic renal failure in children and, in the long run, most cost effective, it results in the need for staff intensive dialysis (i.e., By the time we are fully familiarized with the particular idiosyncracies of a small child on hemodialysis they are ready for transplantation, and we are solving the problems of the next child to be referred here). Secondly, the referral pattern outlined above reflects the perceived and real need of physicians around the country for a highly skilled and experienced unit for their small patients in renal failure. Since renal failure in tiny children is, thankfully, relatively rare, it is difficult for the vast majority of institutions to develop the technologies and experience necessary for effective patient care. Diluting the patient care experience in this highly specialized area to many different centers around the country would undoubtedly lead to a deterioration in patient care standards. Discouraging highly specialized facilities from accepting the most complex patients through financial disincentives would surely produce this unwanted result. Finally the referral patterns we recognize reflect the sophistication of many parents of small children with chronic uremia. A large number of patients (approximately 40% of children under age 5 years) come to us by parental insistance and persistance after the parents have been told that no local therapeutic options exist. Since transplantation in young children is identically as successful at transplantation in older children and adults (see manuscript No. 1), this represents a medical information gap urgently requiring rectification. We anticipate that this manuscript and other writings in the area of renal failure care for small children will bring more referrals to institutions such as ours. In fact, our referral rate for children under age 5 years has doubled since 1978. We wish to remain in a position to provide this service as increasing demands are made upon our special resources. This would require recognition of our unique capacities and problems by your committee.

It is most important that we point out the needs of small children in renal failure. Dialysis treatment is not only staff intensive but is, of necessity, laboratory intensive. The changes in body chemistry are more extreme in small children on dialysis and demand close monitoring for safe treatment. Further, problems encountered frequently in small children are rare in adults. For example, 3 of the 8 children currently on hemodialysis at the University of Minnesota have serious seizure disorders. Since dialysis treatments markedly influence blood levels of anticonvulsant drugs, careful monitoring of these levels is mandatory. These are expensive laboratory tests which are not adequately considered in present reimbursement plans.

One additional point deserves mentioning. We are convinced, based on our recent studies (Kidney International 21:486-491, 1982, manuscript No. 2* enclosed) that the central nervous systems of babies with uremia are at risk and that earlier transplantation than heretofor carried out may be critical in avoiding intellectual deterioration of these patients. We would hope that reimbursement strategies are not developed which would make these new patient care considerations difficult to carry out. Surely this would stifle the inculcation of improved approaches to the solution of difficult problems. Look at another way, some children are considered poor candidates for transplantation because of their small size and are maintained on long-term (usually peritoneal) dialysis in painfully slow efforts to have these children grow bigger and stronger. By developing successful approaches to transplantation in infants, we are hoping to alleviate this prolonged dialysis approach which often leads to self fulfilling prophesies that the child, too small to be transplanted, will die on dialysis. It is in these developmental areas that expenses are high. By making transplantation of small babies safe and effective dialysis costs will fall since time on dialysis will be markedly curtailed and in the end the approach will be cost effective. By failing to recognize the unique role certain dialysis-transplant centers play in treating the most difficult patients and in developing these improved treatment approaches, the present reimbursement plan runs the very grave risk of limiting both medical and economic progress.

We can understand the overall philosophy expressed in the proposed changes in reimbursement strategies for dialysis services. However, we feel strongly that certain institutions providing specialized and unique patient care resources for complex patients will be penalized by these strategies. The need for efficiency and cost-effectiveness is clear to us. However, certain patient care situations simply do not lend themselves to the proposed reimbursement procedures. The ultimate cost effectiveness and medical benefits of renal transplantation in small children should not be threatened because brief periods of dialysis in preparation for transplantation are necessarily, on a per treatment basis, expensive. Institutions providing special care facilities should be reimbursed at cost.

Thus, we strongly urge your committee to consider exceptions to the present reimbursement plans based upon a given institution's ability to document their special roles in the End-Stage Renal Disease Program.

Sincerely,

S. Michael Mauer MD.

S. Michael Mauer, M.D.
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Head, Pediatric Dialysis Program

Robert L. Vernier, M.D.
Professor of Pediatrics
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Professor and Chairman
Department of Surgery
Director, Renal Transplant
Program

William Krivit, M.D.
Professor and Chairman
Department of Pediatrics

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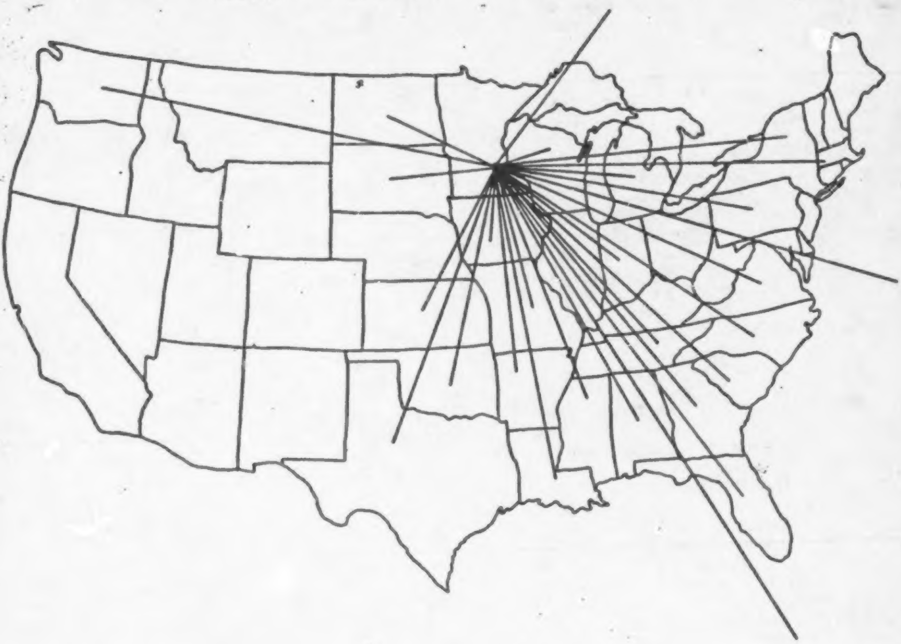
*Retained in subcommittee files.



GEOGRAPHICAL DISTRIBUTION OF U. OF M. PEDIATRIC KIDNEY TRANSPLANT RECIPIENTS

Figure 1. Referral Base for Pediatric Dialysis-Transplant Program at University of Minnesota as of December 1978.

RENAL TRANSPLANTATION IN CHILDREN AGES 1-5 YEARS: REVIEW OF THE UNIVERSITY OF MINNESOTA EXPERIENCE

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From the Departments of Pediatrics and Surgery
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For

Conference on Chronic Renal Disease:
Unique Problems of the Child with Renal Failure
National Institutes of Health
March 5-6, 1981

INTRODUCTION

The reviews of the Dr. Barrett and colleagues (1) and Dr. Broyer (2) in this symposium admirably set the background for the presentation of our experience in the transplantation of children age 5 years and under. In this report we will compare our experience with that of Barrett and Broyer to support our view that renal transplantation is feasible and is the preferred therapy for end-stage renal failure in the young child.

The causes of chronic renal failure (CRF) in our population of young children are similar to those described from other centers (Table I). The notably different lesions causing CRF in this population, as compared to older children and adults, include hypoplasia-dysplasia, obstructive uropathy (38%) and congenital nephrotic syndrome (29%). Since these disorders do not recur in the transplanted kidney, one of the concerns commonly faced after transplantation in older children and adults is obviated.

Dr. Barrett emphasized the difficulty of achieving acceptable growth in young children with CRF, despite aggressive efforts to provide optimal nutrition, acid-base balance, and to prevent bone disease. Our parallel experience has led us to conclude that if, despite optimal management, growth does not occur for 6-12 months, transplantation may be warranted. Further procrastination and delay are unlikely to result in a larger or stronger transplantation recipient.

The results of long-term dialysis treatment in small children from the European Dialysis and Transplant Registry and the Hôspital des Enfants Malades (2) also parallel our own and are discouraging for these small patients, their families and health care teams. Mortality is high, growth is generally poor, vascular access is technically difficult and bone disease is frequent and often severe.

Although not discussed in detail by Dr. Broyer (2), it is our experience that the emotional stresses of chronic dialysis on the small child and their families are enormous and the costs of dialysis, nursing care being more intensive, are extraordinarily high. In discussions with Dr. Broyer (personal communication) it is clear that, given more abundant cadavers or living relative donors, his group would greatly prefer transplantation to long-term dialysis in these young children.

Dr. Barrett's data has demonstrated a steep downward slope of survival for children with congenital disorders in the first year of life and a continuing considerable loss of life over the next four years. Although there is little evidence of success in the transplantation of children much less than one year of age, our experience with children 1-5 is encouraging. The remainder of this paper will review that experience which we believe supports our view that early transplantation is appropriate therapy for CRF in the young child.

Patients

We have transplanted 42 children (26 boys, 16 girls) ages 1-5 years ($\overline{X}$ = 3.3 years, range = 0.9 - 5.9 years, median 2.9 years) between 1970 and 1981. The original diseases are listed in Table I. All children but two were growth retarded (more than 2 SD below mean for chronologic age) at the time of transplant. Most had mild to severely delayed psychomotor development. One child with hypoplastic-dysplastic kidneys developed severe deterioration in neurologic function despite only moderate uremia and was transplanted in an effort to reverse this process. All failed conservative management. All but three children received hemodialysis for an average of two months prior to transplant. In no case was transplantation performed because of an inability to maintain the child on dialysis.

Donor Source

Thirty-five patients initially received living related donor (LRD) grafts, 34 from parents (21 mothers and 13 fathers) and one from a grandmother. The remaining 6, with no suitable family donor, received cadaver donor (CD) grafts which, for the last 5 years, have been matched for at least 2 of 4 HLA A and B antigens. All children but one received adult donor kidneys. One received two kidneys from a 5-year-old donor. No effort was made to search for pediatric cadaver donors, since such donors are rare and waiting for a well-matched pediatric donor would greatly prolong dialysis. The advances in transplantation techniques (see below) have permitted transplantation of adult kidneys into children as small as 5400 gm without great technical problems.

Surgical Strategies

Since the kidneys were all placed intra-abdominally in these small children (3,4), every attempt was made to perform a one-stage procedure including nephrectomy (where necessary), splenectomy (performed in all but one child), and transplant in order to avoid two major intra-abdominal operations. Exceptions included two children requiring urgent nephrectomy for malignant hypertension and children with congenital nephrotic syndrome (CNS) and anasarca. In the latter situation 6-10 weeks were allowed following nephrectomy for recovery from hypoproteinemia, hyperlipidemia, hypogammaglobulinemia, hypercoagulability and malnutrition. Three children, two with CNS and one with steroid resistant nephrotic syndrome became anuric with vigorous ultrafiltration on hemodialysis, thus undergoing spontaneous reversal of nephrotic syndrome and avoiding a two-stage procedure. In the past all children with external urinary diversions underwent a two-stage procedure with removal of the kidneys and ureters in order to eliminate infectous foci and avoid the risk of sepsis following the institution of high dose immunosuppression. More recently we have begun to take down loop cutaneous ureterostomies to re-establish a normal urine flow prior to transplantation in children who were relatively free of recurrent infections. This reconstruction substitutes a relatively minor procedure for a major intra-abdominal procedure (nephrectomy), allows distension of any unused bladder, decreases the difficulty of ureteroneocystostomy at transplant, and allows the child a period of bladder control training which simplifies the post-transplant management period.

Intraoperative Management

These small children are monitored intraoperatively for central venous pressure (CVP) using lines placed via jugular veins at surgery or Hickman catheters which were previously placed as dialysis access devices. The arterial limb of modified Scribner shunts or percutaneously placed arterial lines are used to monitor blood pressure and arterial blood gases. Great care is taken to maintain normothemia by warming the operating room, the patient, and all abdominal lavage solutions and wet packs. Kidneys are perfused with warm solutions prior to clamp release. The vascular anastomoses (end to side) are made between donor renal artery and vein and the recipient aorta and vena cava, respectively. Before the vascular clamps are released, the CVP is acutely raised to 10-12 cm H_2O in order to insure adequacy of the vascular volume needed to fill the new kidney.

The ureteral reimplantation is a standard Ledbetter-Politano tunneling technique. The large bowel is tacked to the upper pole of the kidney in order to provide access to the lower pole for percutaneous graft biopsy, should this become necessary. The kidney may appear hypoperfused during abdominal closure and may require repositioning to avoid vascular kinding and compromise of renal blood flow.

Post-Operative Care

Urine output may be low in these small patients for the first few post-operative hours but usually increases spontaneously. It is important to avoid severe hypertension and fluid overload during this critical period. The CVP alone is a wholly inadequate monitoring technique in these tiny patients; and other parameters including BP, pulse, frequent chest x-rays and arterial blood gases must be followed in addition to CVP in order to avoid fluid overload. These children may be severely hypertensive and in pulmonary edema with CVP's in the 2-5 cm H_2O range. Large urine outputs are frequent in the first 24 hours post-operatively, and monitoring of urine and plasma glucose is important to avoid hyperglycemia and consequent osmotic diuresis. We switch from a 5% to a 1% glucose urine replacement solution if the urine glucose becomes positive and/or hyperglycemia develops. Immunosuppressive management and treatment of rejection episodes routine to our institution have previously been described (4,5).

Patient Survival

We have lost six children in this series. The causes of death have been varied (Table II) and theoretically preventable in most patients. Two splenectomized children who were receiving sulfanamide prophylaxis died of overwhelming pneumococcal sepsis. All children are now maintained on once daily penicillin (6). One child died of disseminated chicken pox three years post-transplant. A recent review of this disease disclosed that the continuation of Imuran during the course of this child's illness was probably responsible for his death (7). One child with urine leak died of inappropriate fluid administration and unrecognized pulmonary edema. One child had treatment withdrawn at parental request after acutely rejecting a graft. In retrospect, our handling of this intrafamilial emotional crisis following graft rejection was less than ideal. Thus, the child with Wilm's tumor dying of intra-abdominal postoperative sepsis (Table II) probably represents the only inevitable death in this group since he had advanced metastatic disease at autopsy.

Deaths in these children may be further minimized by experience and consistent application of sound principles of medical and surgical care. Nonetheless, the overall risk of death is not higher for these young children than for older children or adults (Figure 1). Although the number of patients (6) is too small for statistical comparison, the patient survival of recipients with cadaver grafts was essentially identical to recipients of parental grafts. These data support our view that patient survival rates following transplantation in the infants and young children are comparable to those in older children and adults.

Graft Survival

Graft loss is no more frequent in these young children than in older children or adults (Figures 2 and 3), and comparison of these figures indicates that parental and cadaver graft survival were almost identical. As expected, the dominant cause of graft loss was rejection. Acute rejection in these small children frequently presents as a picture of rapidly progressive renal failure which, despite aggressive antirejection treatment, is unremitting leading to total destruction of the graft within a few days to a few weeks. Six of the 11 first grafts lost in our series followed this dramatic clinical pattern. Although this relatively violent rejection is, in our experience, more common in small children than in adults, it does not influence the frequency of graft loss (Figures 2 and 3).

Seven children have received second grafts and two third grafts. Of these nine children with multiple grafts, seven are alive with functioning grafts and two are dead. Only one child in this group remains on dialysis because of 100% cytotoxic antibodies following rejection of a maternal graft. Thus, the commitment to provide aggressive care to these 42 young children has generated only a single child who is lingering on dialysis.

Recently the important influence of graft source on graft survival was shown by our associates (8). The data derived mainly from parental grafts showed that male (paternal) donors provided statistically significantly better graft survival (73%) than female (maternal) donors (52%) at 5 years post transplant (8). This may represent subtle sensitization of children to maternal antigens in utero. Whatever the explanation, the tendency toward more frequent maternal donation (21 mothers vs. 13 fathers) represents both societal maternal role expectations and our previously held incorrect belief that maternal kidneys, being slightly smaller, would "fit" better in the abdomen of these small children probably contributed to this donation pattern. In the future we will encourage families toward initial paternal graft donation.

In summary, it is clear from Figures 2 and 3 that, in terms of functional graft survival, infants and small children are excellent transplant candidates.

Growth

The growth patterns of these children after transplantation are now quite well defined (3,9). Given a successful graft and the presence of significant (less than 5th percentile) growth retardation prior to transplantation, all but one of these children showed catch-up growth for the first 1 or 2 post-transplant years followed by normal growth rates. The one exception grew at almost a normal rate (88% of expected growth) in the first 5 post-transplant years. Achievement of normal height for age for these profoundly growth retarded children is unusual (20%), but most approach this goal. Children with multiple severe rejection episodes requiring repeated treatment with high dose steroids and leading to renal insufficiency or multiple transplants grow poorly (3,9). Recently, we have shown that low dose once daily Prednisone ($\overline{X}$ = 0.3 mg/kg/day) does not inhibit catch-up growth and provides only a small growth disadvantage over alternate day Prednisone therapy (10). However, a very significant risk of rejection resulted from switching to alternate day therapy in children who had rejection episodes in the early post-transplant period (10). Thus, we recommend alternate day prednisone only for those children with retarded post-transplant growth who have had no history of transplant rejection.

In summary, growth in most transplanted young children is satisfactory and may be extremely good. Our experience does not support, a priori, that young severely growth-retarded uremic children should be excluded from consideration for transplantation because of the fear that they will remain renal dwarfs.

Development

Most small children with uremia or congenital nephrotic syndrome have mild to moderate delay in psychomotor development (11). One child who developed rapid decline in global central nervous system function prior to transplant remains profoundly retarded after transplant. One child requires special education for retardation which developed post-transplant and was associated with intractable petit-mal seizures. One child with Jeune's syndrome and multiple perceptual problems and seizures remains on dialysis 4 years after loss of her maternal graft and requires special education, although her IQ is close to normal. An additional child's verbal learning has been markedly delayed by severe hearing loss which developed after her second transplant. All other successfully transplanted children have shown catch-up in psychomotor development and, with the above exceptions, all of school age attended regular school, and most are in their appropriate grade.

In summary, the intellectual outcome of successfully transplanted young children has been one of the most gratifying aspects of our experience in the care of the small transplant recipient.

General Thoughts

Clearly, the care of the very small child requiring dialysis and transplantation is highly complex. Experience is a necessary ingredient for success. Since renal failure in childhood is rare and children 5 years of age and under make up only 10-15% of the pediatric renal failure population (2), it would be difficult for any center to gain the experience and maintain the high skill level necessary if many centers undertake to care for these patients. It is thus our view that specialized centers should be developed and that referral patterns established which will foster the maintenance of an effective patient care team. This team should operate in centers with a broad base in pediatrics, including subspecialty interests in nephrology, infectious disease, cardiology, neurology, nutrition, child psychiatry and social work. Broad based surgical representation in transplantation surgery, vascular access surgery, urology, and orthopedics is at least of equal importance. Skilled dialysis and transplant nurses and technical personnel represent essential team components. Information which we have received through personal communication indicates that many centers have been discouraged in their early efforts in this area because the requisite team approach was not established and early failures were thus predictable. It is our estimate that 5 or 6 centers in the USA concentrating on transplantation of small children would be sufficient to meet the national needs.

Many problems remain unresolved. The very long-term outcome of most of these children remains shrouded in the future as few have been transplanted for a sufficient length of time to reach puberty. The problem of graft rejection, yet to be satisfactorily solved, has much greater impact on the small child who does relatively poorly on long-term dialysis. New immunosuppressive treatments such as Cyclosporin A (12) and total lymphoid irradiation (13) are still experimental and pose ethical dilemmas, especially in young children who cannot give meaningful consent. Recent evidence that uremia in the first year of life may have a significant negative impact on the developing brain (11) needs careful examination and may indicate that earlier transplantation may be desirable for maximal developmental potential. Despite the extra effort involved, our results indicate that discrimination against aggressive treatment of the small uremic child on the basis of age or size alone is unwarranted.

TABLE I

CAUSES OF RENAL DISEASE IN 42 TRANSPLANTED CHILDREN

AGES 1-5 YEARS

Hypoplastic dysplastic kidneys	16
Congenital nephrotic syndrome	12
Oxalosis	2
Hemolytic uremic syndrome	2
Infantile polycystic kidneys	1
Cystinosis	1
Rapidly progressive glomerulonephritis	1
Steroid resistant nephrotic syndrome with focal segmental sclerosis	1
Steroid sensitive nephrotic syndrome & interstitial nephritis	1
Jeune's Syndrome	1
Gonadal dysgenesis and glomerulonephritis	1
Wilm's tumor	1
Birth asphyxia: cortical necrosis	1
Chronic glomerulonephritis; Type unknown	1

TABLE II

CAUSES OF DEATH IN 42 TRANSPLANTED CHILDREN

AGES 1-5 YEARS

Overwhelming pneumococcal sepsis	2
Abdominal sepsis following graft artery stenosis repair, Recurrent Wilm's tumor at autopsy	1
Disseminated chickenpox	1
Iatrogenic fluid overload	1
Withdrawal of active therapy following graft rejection	1

FIGURE LEGENDS

Figure 1

Actuarial patient survival curves for patients in three age groups. Numbers above data points indicate number of patients at risk at that time and numbers in parentheses (N) equal number of patients entered into each group in Figures 1-3. Data describes patient survival from the initial point of all first transplants in non-diabetic patients. There are no significant differences between these curves

Figure 2

Actuarial graft survival for all first transplants, regardless of donor source in nondiabetic patients. There are no significant differences between these curves.

Figure 3

Actuarial graft survival for all first transplants from parental donors in nondiabetic patients. There are no significant differences between these curves.

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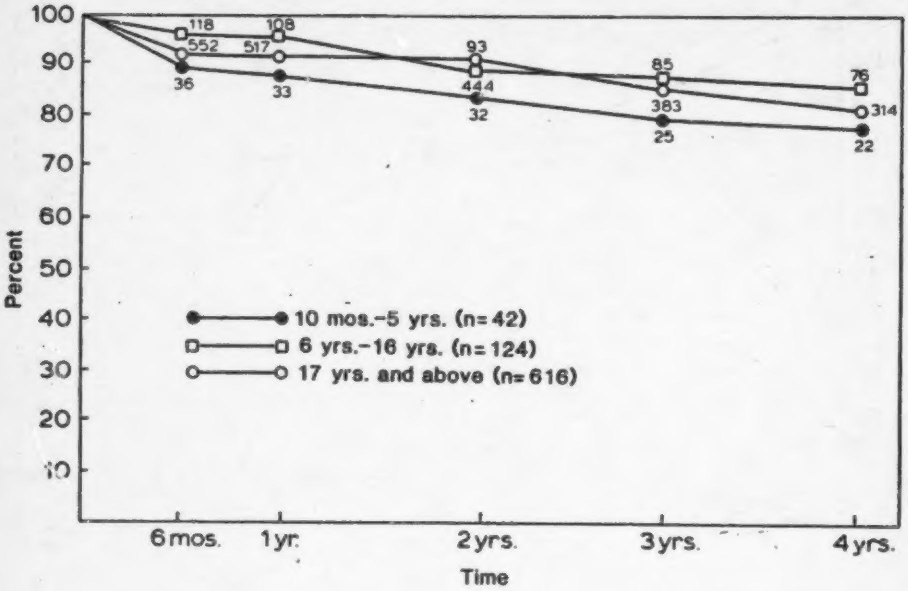
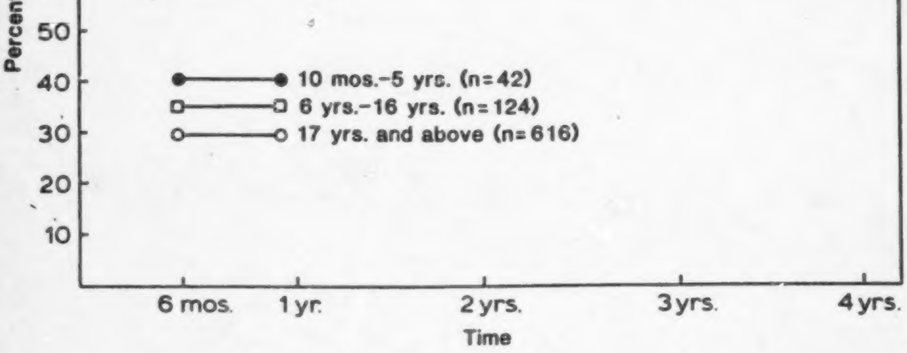
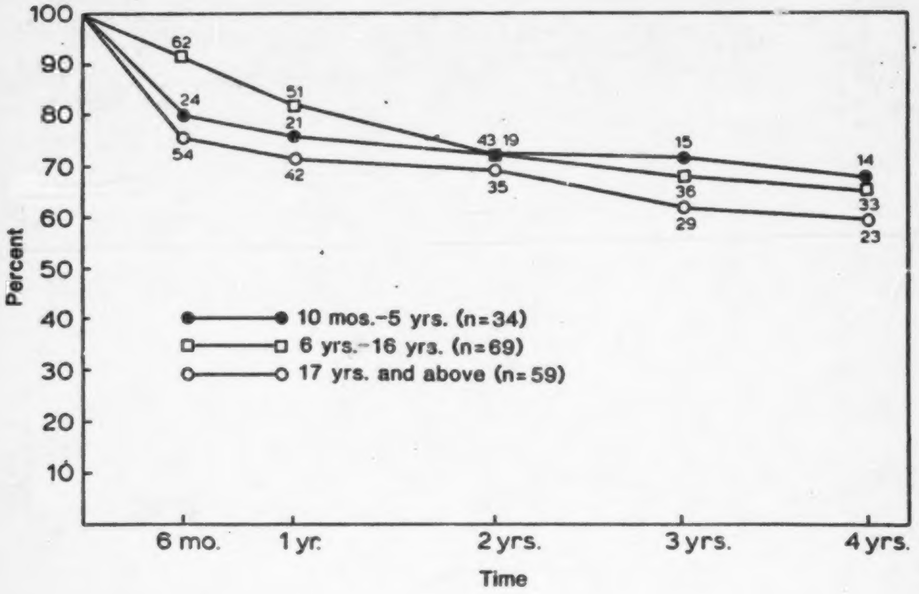
Patient Survival All Donors (Non-Diabetic)



All First Transplants Graft Survival (Non-Diabetic)



Parental Donor Graft Survival – First Transplants (Non-Diabetic)



UNIVERSITY OF MINNESOTA
TWIN CITIES

University Hospitals and Clinics
420 Delaware Street S.E.
Minneapolis, Minnesota 55455

April 28, 1982

Dr. Michael Mauer
Professor of Pediatrics
Head, Pediatric Dialysis Program
Box 491 Mayo
University of Minnesota Hospitals and Clinics

Dear Dr. Mauer:

Our planning and budgets for the Pediatric Dialysis Program are not complete at this time. However, preliminary data used for planning includes an estimate of 1300 runs per year (4 per day or about 25 per week); 21,981 total hours of payroll including regularly scheduled hours (20,462), overtime hours (799), education and orientation hours (720); 0.7 FTE administrative time; and 19% fringe benefit costs. Total estimated salary expense for 1980-81 would be $288,487 or about $222 per run. Costs of supplies, equipment and overhead allocations will probably result in full costs of $444 per run.

These data relate to gross estimates for a separate unit for pediatrics rather than the present combined center for adults and children. Costs could be about $100 per run less if the programs remain together with no changes. However, if a functional separation occurs within the present unit costs may be only $30 less than our $444 estimate.

Please advise if I can provide additional information.

Sincerely,

Donald Van Hulzen
Hospital Director (Interim)

/mh

HEALTH SCIENCES

STATE OF NEW YORK
DEPARTMENT OF HEALTH
ALBANY

DAVID AXELROD, M.D.
COMMISSIONER

RECEIVED
APR 14 1982
DIVISION OF
CHILD HEALTH
K-63

April 9, 1982

RE: BPP-126-P

Dear Ms. Davis:

The New York State Department of Health offers the following comments with respect to the proposed rulemaking published in the Federal Register of February 12, 1982, concerning a prospective Medicare reimbursement system for the End-Stage Renal Disease Program.

The intentions of these regulations, to reduce cost and to encourage the use of home dialysis, are worthy objectives to which we in New York State have been committed in the service we have provided to our chronic kidney disease patients. However, we are not convinced that the proposed preferred reimbursement method is the most effective means of achieving these goals. In fact, we believe that the immediate effect of this rate setting methodology will be to drive up the cost of home dialysis and, over the long term, to foster disincentives for increased home dialysis care. This will be particularly true in New York State, since implementation of these regulations will jeopardize the continued existence of our Home Dialysis Assistance Program.

For the past ten years, our State has encouraged and supported the growth of high quality, cost-effective home dialysis treatment through the patient care activities of this program. We have been an advocate of effective home patient service by relieving end stage renal disease patients of the financial burden of their treatment and have effected cost containment in the dialysis industry by negotiating prices with vendors and encouraging competition in the dialysis supply market. As a result, the prices we pay for supplies and equipment are some of the best in the industry and are substantially lower than those reimbursed by Medicare in many other areas of the United States. In fact, several years ago the Bureau of Medicare evaluated this highly successful program and determined that it was a "role model" for other states and organizations seeking to establish a mechanism for the effective delivery of home dialysis patient services. This evaluation of the program was confirmed again in 1981 by the Office of Special Programs of the Health Care Financing Administration.

Further evidence of our commitment to this program is the fact that the State has provided substantial financial support of home dialysis through provision of a special State First Instance Appropriation which has grown from approximately $6 million in SFY 1980-81 to $10 million in SFY 1981-82. For SFY 1982-83, we are requesting nearly $13 million. With these funds, the program provides 100 percent financial coverage for all necessary supplies, medications and equipment needed by home patients and is reimbursed for covered costs by Medicare, Third Party Insurers, and Medicaid. Services not reimbursed are absorbed by State funding. The dramatic increase in State funding for the

Home Dialysis Assistance Program is the result of an increase in patient caseload. Our patient census as of December 31, 1978 was 338 as compared with 713 patients on December 31, 1981. As of today, we are serving 772 patients and we project that our caseload will exceed 800 during this calendar year.

Clearly, all of these data are convincing evidence of a successful and viable program which offers high quality home patient service within a framework of price and cost control. The proposed reimbursement regulations will jeopardize the ability of the State to continue this program as it currently operates. Although patients will be permitted to bill for supplies and equipment directly, the proposed preferred option is for payment to be made only to facilities on a composite rate per treatment basis. Under this method, if the New York State Home Dialysis Assistance Program continues to provide supplies and equipment to home dialysis patients, the program will be required to bill 50 or more facilities for its costs rather than billing Medicare directly. This will place a substantial administrative burden on the program and affect the State's ability to recover, on a timely basis, a large percentage of incurred costs, a negative cash-flow position which the State is not prepared to assume at this time.

We request that these proposed regulations be amended to allow for the continuation of state programs such as New York State's Home Dialysis Assistance Program. Such an amendment should allow a centralized agency to continue to act as a supplier for home dialysis patients and to bill Medicare directly for cost plus administrative overhead and for the incorporation within the rate structure of a separate, reasonable cost payment, on a per treatment basis, to facilities for home dialysis support services. Based on our experience as a large-scale, centralized bargaining agent for home dialysis supplies and equipment, we are convinced that this payment option would be more cost beneficial to the Medicare system, facilities and home patients.

We are prepared to meet with you and your staff at any time to discuss this payment option as well as the effects of the proposed regulations on the future of home dialysis in New York State.

We appreciate the opportunity to comment on these regulations and hope that you will take our position into consideration before final regulations are implemented.

Sincerely,

David Axelrod, M.D.
Commissioner of Health

Ms. Carolyne Davis
Administrator
Health Care Financing Administration
Department of Health and Human Services
P.O. Box 17073
Baltimore, Maryland 21235

Northern Colorado Kidney Center
1213 Riverside Drive
Fort Collins, Colorado 80524
303-493-7575

April 19, 1982

Congressman Charles Rengel, Chairman
Subcommittee on Oversight
Committee on Ways and Means
Longworth Office Building, Room 1101
Washington, D.C. 20548

Dear Mr. Chairman:

Upon reading the proposed rules related to prospective reimbursement rates for dialysis services it becomes clear that there are numerous factors which have not been given consideration nor adequately amplified in the course of this rather lengthy and critically important document. No one can argue with the legislative intent of these regulations - to encourage more efficient and cost effective delivery of dialysis services and to promote more home dialysis. However, we believe that in the rush to cut costs in this area certain false assumptions have been made which will inevitably have disasterous effects on dialysis units throughout the country, particularly those in rural areas.

Our specific areas of concern are as follows:

1. The area prevailing wage index is seriously flawed in two ways: (1) it is two years old and (2) it results in different reimbursement rates being given to units which have identical labor costs;

2. The funding for CAPD supplies and training is so inadequate that these rates actually serve as a financial disincentive to the placement of patients on CAPD;

3. Both because funding for hemodialysis training is inadequate and because our small unit cannot afford to pay $8,000 for hemodialysis and reverse osmosis machines, we will not be able to afford to send patients home on hemodialysis;

4. The significant differences between the economic realities of small versus large units have not been taken into consideration;

5. All of the above considerations mandate that, to survive, we must not only decline to send more patients home but should ask the 30% of our patients that are already at home to return to center dialysis;

6. Finally, if these regulations are placed into effect and we do not receive additional funding, we will be forced to close the door of our dialysis unit which serves Northern Colorado, Southern Wyoming, Western Nebraska and Western Kansas.

These problems are considered in greater detail in the following pages.

Thomas A. Haygood, M.D., Medical Director / Marrae T. Martin, Administrator
Bio-Medical Applications of Fort Collins, Inc. / A subsidiary of National Medical Care, Inc.

REIMBURSEMENT RATES

In December of 1981 when Secretary Schweiker's office announced the average payment figures for dialysis reimbursement at $132.00 and $128.00, we felt that by careful management we could meet our costs at these new levels. We came to discover, however, that these average payment figures are to be weighted heavily by area prevailing wage indexes. While this metholology increases the reimbursement rates in areas such as New York and San Francisco to levels equal to or above what they are currently receiving it, in turn, decreases the reimbursement rates for rural units such as ours, making it impossible for us to survive. We have identified three basic problems which have contributed to this state of affairs.

I. Data Base

It appears that the audits which were done to determine the average costs of providing dialysis, both in-center and home, were conducted under severe time constraints and only on the largest programs in the country. This resulted in a lower cost figure for both modes of dialysis than if smaller facilities had been included in the audit. A second major problem is that the derived cost data ($133.00 and $108.00) is three years old, having been taken from late 1978 and early 1979 cost reports. Thirdly, increases for labor, plant operations, supplies and other inflation prone costs were not taken into account and render the cost data used to formulate the new rates arbitrary and inaccurate. Lastly, the median rather than the average costs for these programs was chosen, distorting the costs of home dialysis and further decreasing the prospective rates.

II. Area Wage Index

All would agree that it must cost less to perform dialysis in Fort Collins than it does in San Francisco. Therefore, it seemed quite reasonable to factor the reimbursement rates based on the cost of doing dialysis in each geographical area. However talking to the HCFA people in Washington we discovered that they are using figures from the Bureau of Labor Statistics which are eighteen months old and do not reflect the escalation in nursing salaries which has taken place in the last twelve months. Take for instance what has transpired in our local area since October of 1981.

Up until October of last year salaries for our unit were competitive with those at the local hospital and slightly below (by 60¢ to 70¢ per hour) salaries in dialysis units in Denver, sixty miles away. In October 1981 our local hospital increased overall nursing salaries 20%. This sizable salary adjustment posed a critical problem for our unit for a number of reasons. Because the unit is fairly small (20 in-center patients and 9 home patients) we do not have the option of hiring LPNs instead of RNs. In addition, due to the limited pool of RNs in this area we are in close competition with the hospital for staff and subsequently must keep our salaries at least relatively competitive. As a consequence our salaries are now equal to and in some instances higher than those of dialysis units in Denver (See attached analysis - Exhibit A). Unfortunately, as will be seen in the next section, although our labor costs are the same as Denver we will be paid considerably less than the Denver units.

EXHIBIT A

SALARY COMPARISON *

	Denver			25 min. from Fort Collins Hospital	in Fort Collins Hospital	NCKC
	Unit A	Unit B	Unit C			
**RN's	$71.00 $7.10/hr.	$79.00 $7.90/hr.	$79.00 $7.90/hr.	$86.60 $8.66/hr.	$88.70 $8.87/hr.	$84.60 $8.46/hr.
**Technicians	$60.00 $6.00/hr.	$56.00 $5.60/hr.	$57.50 $5.75/hr.	$68.50 $6.85/hr. (LPN)	$62.80 $6.28/hr. (LPN)	$55.00 $5.50
Head Nurse	$110.00 $11.00/hr.	$110.00 $11.00/hr.	$105.00 $10.50/hr.	$110.00 $11.00/hr.	$110.00 $11.00/hr.	$103.00 $10.30/hr.
***Cost/TX Direct Patient Care Staff	$20.08	$20.42	$20.12	$22.09	$26.15	$20.21

*Cost of doing 12 treatments - Two shifts with 6 patients/shift.
- Staff working a 10 hour day.

**Hourly rates shown are entry level - No experience.

***Other personnel costs (indirect patient care) vary depending upon the size of the unit. However, when these costs are taken into consideration, the cost/TX varies only $1.00 - $2.00/TX.

III. Differential in Reimbursement Between Denver and Fort Collins

Using the out of date information provided to HCFA by the Bureau of Labor Statistics created a differential in the reimbursement rate of $14.00 per treatment between units in Denver ($128.00 per treatment) and Fort Collins ($114.00 per treatment). Yet the actual average hourly patient care labor rate varies by only pennies and certainly does not justify a $14.00 differential in the reimbursement rate. Besides the fact that this is patently unfair, these incongruities in reimbursement will serve to discourage rather than to promote home dialysis. In the following sections we will attempt to illustrate this fact.

IV. Recommendations

A prospective reimbursement system should be based on complete, accurate and timely cost data. We propose that HCFA should undertake a new, in depth audit of facilities costs with close participation of the facilities and intermediaries in order to obtain valid cost data. Secondly it would seem reasonable to include provisions for legitimate geographical differences in labor and other cost factors. If a wage index is to used, every attempt should be made to insure that the figures accurately reflect current salary scales and that inflationary factors and locale differences (urban versus rural) are taken into account.

INCREASED DISINCENTIVES TO HOME DIALYSIS - CAPD

As stated above the new regulations are designed to promote less costly home dialysis over the more expensive in-center dialysis. One would think that paying the same rate for all treatments, whether at home or in-center, would inevitably provide an incentive to send more patients home. This is based on the assumption that what the unit loses on in-center dialysis will be more than made up by profits on home patients. However this premise is seriously flawed. In the following analyses we will first show that the new rates will actually decrease our ability to send new patients home and will even cause us to close our doors. After demonstrating the disasterous results of the new rates, we will then explain what we believe to be the defects in HCFA's methodology which leads to these unfortunate consequences.

In the following examples we are using only CAPD patients to illustrate our point due to the lack of adequate information as to how home hemodialysis will be reimbursed.

I. Incentives to send new patients home?

Let us start with the most probable scenario. Take a unit such as ours with 20 in-center hemodialysis and 5 home dialysis patients on CAPD. Let us assume that the unit gets two new patients (both good candidates for CAPD). Is there a financial incentive to send these patients home? We have constructed a flow chart to demonstrate the consequences of putting these patients on either modality (See Exhibit B). On the left, the two new patients are sent home on CAPD, whereas on the right, these patients are kept in-center. The results of this exercise indicate that under the new rates we would suffer greater losses by sending these two patients home than if we had kept them in-center (See Appendix I, II and III for more detailed cost analysis).

EXHIBIT B

20 IN-CENTER & 5 CAPD

$20.61 loss/TX and $9.10 profit/TX = $11.51/Tx net loss ($35,928/year)
(20 center pts.)   (5 CAPD pts.)

2 new patients, both
sent to CAPD.

↓

27 patients

$20.61 loss/TX and $12.78/TX profit = $7.88/TX net loss
(20 in-center pts.) (7 CAPD pts.)

2 new patients, both left
in center.

↓

27 patients

$9.83 loss/TX & $8.27/TX profit = $1.56/TX net loss
(22 center pts.) (5 CAPD pts.)

Summary: On the basis of the new reimbursement rates our small center would be better financially keeping new patients in the center and not sending them home.

APPENDIX I

COST CONSEQUENCES OF 20 IN-CENTER PATIENTS & 5 CAPD PATIENTS

REVENUE:
20 in-center = 3120 TX x $114.00 = $355,680/year

EXPENSES:
20 in-center - expenses - $420,000 (approximately)

LOSS = $64,320 per year or $20.61/TX
The unit has 20 in-center patients and is receiving $114.00/TX which amounts to $355,680 in revenue per year. Since the unit's expenses for providing patients with dialysis services are $420,000 per year, we will have a loss of $64,320 or $20.61/TX

REVENUE:
5 CAPD patients = 15 TX per week @ $114.00 = $1,710/wk x 52 wks = $88,920

EXPENSES:
5 CAPD patients = 140 exchanges/wk @ $8.32/exchanges = $1,164/wk x 52 wks = $60,528

PROFIT: $28,392 or $ 9.10/TX
The unit also has 5 CAPD patients who bring in an additional $28,392 revenue per year, (This is assuming that the unit can negotiate a good price for supplies) or $9.10/TX. The 5 CAPD patients thereby decreases the unit's loss to $35,928/year or $11.51/TX.

APPENDIX II

COST CONSEQUENCES OF 20 CENTER PATIENTS
& 7 CAPD PATIENTS

REVENUE:

20 in-center patients = 3,120 TX x $114.00 = $355,680/year

EXPENSES:

20 in-center - expenses - $420,000 (approximately)

LOSS = $64,320 per year or $20.61/TX

Unit gets two new patients and puts them on CAPD. As in Appendix I, the unit is still losing $64,320 per year or $20.61/TX on the 20 in-center patients.

REVENUE:

7 CAPD patients = 21 TX/wk @ $114.00/TX = $2,394.00/wk x 52 = $124,488/year

EXPENSES:

7 CAPD patients = 196 exchanges/wk @ $8.32/exchange = $1,630/wk x 52 = $84,760/year

PROFIT: $39,728 per year or $12.73 per TX

Unit now has 7 CAPD patients who bring in additional revenue of $39,728 or $12.73 /TX decreasing yearly loss to $24,592 or $7.88/TX. Nonetheless we are still losing money.

APPENDIX III

COST CONSEQUENCES OF 22 IN-CENTER PATIENTS & 5 CAPD PATIENTS

REVENUE:
22 in-center = 3,432 TX x $114.00 = $391,248

EXPENSES:
22 in-center expenses = $425,000

LOSS = $33,752 per year or $9.83/TX
The unit gets two new patients and keeps them in-center resulting in increased revenue totalling $391,248 per year. The center's total expenses would go up slightly ($5,000) due to supplies for additional treatments. However all other costs stay relatively the same for a total of $425,000 in expenses or a loss of $33,752 per year or $9.83/TX.

REVENUE:
5 CAPD patients = $88,920 revenue
$60,528 expenses
PROFIT: $28,392 or $8.27/TX
The 5 CAPD patients are still bringing in the same additional revenue as in Appendix I of $28,392 per year or $8.27 per TX. This decreases the unit's loss to $5,360 per year or $1.56 per TX.

Summary: We lose less money (but never break even) by keeping new patients in the center.

II. Incentives to encourage current in-center patients toward home dialysis?

We believe that the success of the composite rate depends upon the unit's ability to maintain a particular ratio between in-center and home patients. According to the logic of the methodology, moving patients out of center should be accompanied by a reduction of in-center costs and a minor loss of revenue which will be made up by increased revenues on home patients. The success of this logic however rests on two assumptions. First, that the loss of in-center patients will decrease overall in-center costs, particularly in the area of salaries - less patients requiring less staff. The second assumption is that the reimbursement for home treatments is high enough to make up for the loss. Unfortunately this is not the case. In our particular situation (I am sure this applies to other small units) whether we have seventeen or twenty-five in-center patients our salaries, supplies and other administrative costs remain relatively the same and our current reimbursement rate ($114.00) is totally inadequate for meeting these costs. Consider the accompanying example (Exhibit C) which illustrates the dilemma of a unit such as ours were it to begin moving patients from center to home in an effort to achieve the ideal ratio. We start with twenty in-center and five home patients and move two patients to home dialysis. Where the unit was formerly losing $11.51 per treatment, moving two patients to home dialysis increases the units loss to $17.24 per treatment. Pushing this example even further and supposing the unit was somehow able to achieve a 40% split we still find the unit suffering a substantial loss.

III. Incentives to bring home patients back into center?

If one looks at the figures there is actually more incentive for a small unit to bring its home patients back into center than to send in-center patients home. In Exhibit D, we show that with seventeen in-center patients and eight home patients the unit is losing $21.00 per treatment. If the unit brings those eight CAPD patients back into the center the unit would make a modest profit of $1.00 per treatment.

Why is all of the above happening?

1. The inaccuracies, inconsistencies and ambiguities of the methodology have resulted in reimbursement rates for in-center dialysis which are too low.
2. The methodology is biased toward larger units in urban areas with high incidence of end-stage renal disease. The higher patient population in these areas make it possible for units to maintain a steady in-center population and still send patients home. Units in rural areas, however, with more sporadic patient population will have a much more difficult time retaining in-center patients and have fewer financial resources to withstand significant decreases in cash flow.
3. No consideration has been given to the fact that dialysis supplies for CAPD are much more expensive than those for hemodialysis yet units are being reimbursed at the same rate for both.
4. The additional costs of providing support monitoring for home patients have not been considered.

IV. Reimbursement for Home Training

Given the cost of supplies and labor to train a patient in this modality the rates as proposed are completely inadequate and most facilities will lose money trying to train patients for the home setting.

V. Recommendations

There is no reason for CAPD to be factored by the wage index since there is no specific labor component to this modality. Our recommendation is that these treatments should be reimbursed at the national average of $128.00 per treatment. Secondly, we feel that reimbursement for CAPD training is completely inadequate and that a differential of approximately $30.00 per treatment would be justified. Thirdly, we believe that more realistic consideration should be given to the additional support and monitoring costs which will undoubtedly be associated with servicing more home patients.

EXHIBIT D

17 in-center patients & 8 CAPD patients
17 in-center = 2,652/TX x $114.00 = $302,328/year REVENUE
17 in-center = $403,555/year EXPENSE
LOSS = $101,227/year or $38.00/TX

} LOSS = $21.00/TX

8 CAPD patients =
24 treatments/week x $114.00 = $2,736/week x 52 = $142,272/year
224 exchanges per week x $8.32/exchange = $1,864/wk x 52 = $96,928/year
PROFIT: $45,344/year or $17.09/TX

↓ Bring home patients into center.

25 in-center patients = 3900 treatments x $114.00 = $444,600 per year REVENUE
25 in-center patients = $440,995 per year EXPENSE
PROFIT: $3,605 per year or approximately $1.00 per treatment.

Summary: We can begin to break even on the new reimbursement rates only if we could bring all of our home patients back into the center.

INCREASED DISINCENTIVES FOR HOME DIALYSIS - HOME HEMODIALYSIS

Although no specific plan is outlined in the regulations with regard to reimbursement for home hemodialysis, the scanty information we do have leads us to believe that there is little incentive for sending patients home on this modality.

I. Cost of Home Hemodialysis Machine

Under the new regulations, it appears that dialysis units would be required to purchase the machine necessary for the patient to do dialysis at home. These machines and their reverse osmosis units cost approximately $8,000 and for a small unit to purchase such equipment for each patient it trains would be an unbearable expense.

II. Training Rates

Again as with CAPD the reimbursement rate proposed for training patients in this modality provides little incentive to units such as ours. In fact, we lose considerable money on the actual training. As the costs of labor and supplies alone quickly eats up almost the entire amount we would be reimbursed.

III. Aide Payments

It is stated in the regulations that the profit margin which units will realize based on the new reimbursement rate would enable them to pay for home hemodialysis aides if the need arose. However if we assume the cost of a home hemodialysis treatment to be $97.00 (the median cost which HCFA proposed in the rules) and our unit would be reimbursed at a rate of only $114.00, this would leave $17.00 per treatment with which to reimburse aides. It seems unlikely that anyone is going to want to spend five to six hours dialyzing a patient for what amounts to $2.83 an hour.

IV. Experimental Programs

Details as to what will happen to patients who have participated in special experimental programs are conspicuously absent in the new regulations. Many of these patients were guaranteed payments for home aides through May 31st of 1987. All of the patients we currently have on home hemodialysis are part of the Utah Home Hemodialysis Program and we are currently paying aides approximately $41.00 per run and spouses $20.00 per run. These assistants are also being paid $4.00 per hour and $2.00 per hour respectively while training and mileage incurred during the training period is covered. Should the reimbursement rate for these special programs be cut, there is the liklihood that all of the aides and many of the spouses would not continue in the program and that the unit would be forced to take patients off home dialysis and bring them back into the center.

V. Support and Monitoring Services

As with CAPD, the additional expense of providing support and monitoring services for these home patients has been overlooked.

VI. Recommendations

In order to truly support and encourage home hemodialysis we feel that patients who are currently on experimental incentive programs should continue to be reimbursed as promised or that a more realistic reimbursement rate be given to units enabling them to pay aides. Secondly, a more reasonable method of reimbursement for the purchase of equipment should be established. Perhaps units could be reimbursed up front for the purchase of machines or paid off in two or three large payments. As with CAPD, training rates should be increased to more accurately approximate costs and provide greater incentives for units to home train. Lastly, some incentive program for patients should be established. Suggestions in this area have included providing relief to home dialysis patients with funding to pay for additional utility bills or a special income tax deduction if family members assist with home dialysis. In addition consideration should be given to allowing facilities to include, as a legitimate cost, the development of this type of incentive program.

EXCEPTION PROCESS

The regulations clearly state that the exception process will be changed dramatically. For many rural units this will be the only chance they have at survival so we feel that it is critical for regulations in this area to be clearly spelled out.

I. Criteria for a justified exception.

As the regulations are currently written the criteria for justified exceptions are extremely vague. Questions still unanswered include: What comprises a geographical area?, What does the government consider to be "substantial hardship?", Will recent increases in labor costs as noted earlier be seen as a valid argument for justifying costs in excess of payment rates?

II. Timeliness, resources, and exception reserve.

Due to the financial hardships some units will be experiencing as a result of the inequities inherent in the reimbursement schema, prompt action with regard to exception requests will be critical. Our concerns focus on three main areas:

A. Timeliness: A specific time frame should be established for responding to exception requests. In consideration of the gross inequities in the new reimbursement rates, exceptions should be made retroactive to the effective date of the regulations.

B. Talent and resources: Exception requests should be reviewed by well trained personnel who are familiar with the intricacies of providing dialysis services.

C. Exception reserve: It has been said that fifteen million dollars has been set aside for exceptions. One questions whether this is really enough to meet the requirements of all the units who will be effected by the new rate adjustments.

In conclusion, we believe that these regulations are poorly conceived and will ultimately serve to restrict the access of patients to life saving care by controlling the availability of dialysis services. We would urge the Health Care Financing Administration to carefully reevaluate the ramifications of the proposed reductions. The regulations impose unconscionable fiscal burdens upon rural units and the patients whose lives they are gambling with.

Sincerely,

T Haygood

Thomas A. Haygood, M.D.
Medical Director
Northern Colorado Kidney Center

Marrae T. Martin

Marrae T. Martin
Administrator
Northern Colorado Kidney Center

Thomas A. Haygood, M.D., P.C.
Medical Director / Northern Colorado Kidney Center
Nephrology
Internal Medicine

April 22, 1982

Congressman Charles Rengel, Chairman
Subcommittee on Oversight
Committee on Ways and Means
Longworth Office Building, Room 1101
Washington, D.C. 20548

RE: Regulation BPP-126-P

Dear Mr. Chairman:

We are sending under separate cover to you our comments on the proposed changes in the reimbursement rates for chronic dialysis (BPP-126-P). My purpose in writing this letter to you is twofold: first, to describe the practical implications that implementation of these regulations will have on our dialysis unit and, second, to provide a summary of the lengthy comments that we are sending you under separate cover.

EFFECTS OF CLOSING: THE MEDICAL SERVICE AREA

The effects of such a closure would be threefold: (1) the medical impact on our large service area would be severe, (2) the effect on our patients would be devastating and (3) the negative effects that these reimbursement rates would have on dialysis nationally are frightening.

We are currently the only dialysis unit offering a full range of services that exists from Denver to the south, Kansas City to the east, Western Nebraska and Western Kansas would lose a major referral center. The Northern Colorado Kidney Center serves five primary functions: first, we perform life saving, chronic dialysis for patients whose kidney function has irreversibly ceased. Second, we serve as a diagnostic and treatment referral center for all types of kidney disease. Thirdly, we provide artificial kidney treatments for patients whose kidneys have temporarily shut down and who need artificial kidney treatments to sustain their lives until their kidney function returns. These patients are usually critically ill with multiple problems such as shock, pneumonia and heart failure in addition to their kidney problems. They are usually so ill that they would be untransferrable to Denver hospitals. Fourth, the presence of a sophisticated medical facility such as the Center serves as a magnet to draw other physicians with specialty skills into this rural area. Fifth, the Kidney Center serves as an integral part of the Family Practice Resident Training Program at Poudre Valley Hospital and, to a lesser degree, at Weld County Hospital. In this way, we are training the educating the future family practitioners of Colorado to become better equipped to deal with patients with all types of kidney diseases. All of these activities will come to a screeching halt if the reduced H.H.S. fee schedules are implemented.

1120 E. Elizabeth, Bldg. G, Ft. Collins, CO 80524 / 303-493-7733
1601 25th Ave., Greeley, CO 80631 / 303-353-4085

EFFECTS OF CLOSING: THE LIVES OF THE DIALYSIS PATIENTS

In addition to decreasing the availability and the level of sophistication of medical care for patients with kidney disease throughout the area, the closure of our unit would have a second major effect. It would produce a profoundly detremental influence on the lives of the chronic dialysis patients themselves. Just the threat of closure of their unit has already produced significant stress and anxiety amongst these unfortunate patients. At the very best, they would have to drive to Denver three times a week for treatment - an hour and a half trip. At worst, some of them will not be able to either find the necessary stamina or means to make the drive, and could die.

Many of our patients are elderly in their 60s, 70s and occasionally 80s. Many of their spouses are as old and infirm as the patients. These elderly patients have no means of transportation other than local volunteers who can bring them from Loveland to Fort Collins or from Greeley to Fort Collins. Part of their transportation system also includes the local Care-A-Van system which operates in Fort Collins. I appreciate that where there is a will there is a way, nonetheless I cannot imagine how the logistical problem of transporting these senior citizens to Denver would be solved. They would have to be transported there (commute an hour and a half). Some would have to wait in the dialysis center for close to five hours and then transport them back again all of which takes up entire day. This would have to be accomplished six days a week, on two or three different shifts, to more than one dialysis unit.

SUMMARY OF PROBLEMS WITH THE PROPOSED

CHANGES IN DIALYSIS REIMBURSEMENT

AREA PREVAILING WAGE RATES

PROBLEMS:

1. The data is two to three years old;
2. Labor costs are the same in Fort Collins as in Denver but we will be paid $18.00 less per treatment.

RECOMMENDATIONS:

1. Either have current data or do not use the area prevailing wage rates;
2. Establish a maximum differential between urban and rural dialysis units;
3. Allow reality to intrude into the area wage rates by taking the unrealistic age of the data into account when granting exceptions.

INCREASED DISINCENTIVES TO CAPD

PROBLEMS:

1. We would lose money by sending patients to home dialysis and it would be better for our dialysis unit financially if we keep all patients in our center;
2. Whatever mix of home and center based patients we establish, we would still lose money and could not afford to stay open;
3. The cost of CAPD supplies is higher than that of hemodialysis supplies but they are reimbursed at the same rate. The savings in labor costs which accrue from not doing dialysis in a center will not make up for the in-

creased costs of CAPD supplies over hemodialysis supplies;

4. Reimbursement for training CAPD is inadequate;
5. Labor component which has been factored into CAPD but has nothing to do with CAPD only serves to unjustifiably lower the reimbursement rate;
6. Cost estimates that we have made in the body of our report are probably worse than enumerated since we have not included increased administrative and new cost accounting burdens which have been added by the new regulations.

RECOMMENDATIONS:

1. Increase money for center dialysis;
2. Increase money for CAPD;
3. Increase money to adequately reimburse for home training costs;
4. Increase money for the additional costs of supporting patients at home as well as in increased administrative overhead mandated by the government;
5. Remove the area wage component from reimbursements of CAPD and reimburse CAPD at a national average of $128.00 as everyones costs will be the same.

INCREASED DISINCENTIVES FOR HOME HEMODIALYSIS

PROBLEMS:

1. Small units cannot compete in economy of scale with large units;
2. Small dialysis units will be unable to finance the purchase of $8,000 dialysis and reverse osmosis units;
3. The costs for training patients for hemodialysis are inadequately funded;
4. The money left to pay for home aides is totally inadequate as a $17.00 per treatment rate comes out to $2.83 per hour ($114.00 reimbursement rate minus our supply costs alone);
5. As with CAPD, there is no funding for the increased support facilities that the dialysis unit will have to provide home patients;
6. There is no funding to cover the increased administrative costs mandated by the government.

RECOMMENDATIONS:

1. The government should pay for the costs of home hemodialysis machines;
2. Increase funding for home training;
3. Increase funding for increased patient support services;
4. Increase money for administrative overhead which is mandated by the government in terms of record keeping.

EXCEPTIONS

PROBLEMS:

1. The meaning of "hardship to patients" and "geographic areas" is not defined;
2. We have been told by HCFA that our labor costs, which are higher than the two year old data from the Department of Labor would indicate, will not be counted in the exception process;
3. It is not clear how long exception will take to be granted and we are concerned that an exception might not come in time to prevent us from closing.

RECOMMENDATIONS:

1. Define more precisely under what conditions exceptions will be granted;
2. Make any exception granted retroactive to the time that the new regulations start;
3. Mandate a limit on the time that it takes to grant an exception;
4. Make sure the personnel who supervise exceptions are well trained which may not be if just the local Medicare personnel pass on exceptions;
5. Insure that enough money is budgeted for exceptions.

SMALL VERSUS LARGE UNITS

PROBLEMS:

1. Small units do not have an economy of scale that enables them to operate as efficiently as larger units;
2. As an example, since we have a small nursing staff with an RN required for each shift, we cannot economize by replacing RN's with LPN's

RECOMMENDATIONS:

1. Recognize that the HCFA cost data is not equally applicable to all units;
2. Grant rapid exceptions to small, rural units or see them close.

Efforts to decreased our government expenditures and eliminate waste are commendable. But let us not unleash unwise regulations which will be devastating to patients who have had so many other problems.

Sincerely yours,

Tom Haygood

Thomas A. Haygood, M.D.

TAH/mf

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April 6, 1982

Carolyne K. Davis, Ph.D.
Administrator
Department of Health & Human Services
Health Care Financing Administration
P. O. Box 17073
Baltimore, Maryland 21235

RE: BPP-126-P

Dear Dr. Davis:

The Ochsner Clinic accepts in principle the concept expressed in the February 12, 1982 notice of Proposed Rule Making which establishes a prospective reimbursement mechanism for out-patient maintenance dialysis, and which through a composite rate promotes home dialysis. However, these End-Stage Renal Disease Program regulations are considered to be totally unacceptable due to the inadequate rate of reimbursement proposed.

An apparent inadequacy exhibited in the rate-determining methodology is the total disregard of economic realities by the Federal authorities. Failure to adjust for inflation the 1977-79 cost data used to develop the proposed rates is absurd. The fact that a large number of dialysis facilities have opened since 1974 despite a constant reimbursement rate, speaks to a response to a demand for services, not just an ever-increasing ability for facilities to increase efficiencies as the proposed Rules text implies. Indeed, the manner by which many of the facilities with lesser standards achieve their economies should be a concern of the regulators. Even after reasonable cost savings measures have been taken, the cost of providing dialysis services has increased, as have all other factors in our society during the last five years.

Another major concern regarding the methodology is that the average wage index used to determine the labor component of the reimbursement rate is entirely inappropriate when applied to dialysis facilities. Although this index was derived by dividing the local wage level average for all hospital workers by the national average for all hospital workers, it fails to take into account the much higher ratio of skilled to unskilled staff used in dialysis facilities versus hospitals. This characteristic coupled with the fact that nursing salary levels vary so widely nationally upsets the relevancy of the wage index used (see attachment).

An additional area of concern is the reliability of the research performed in accumulation of the cost data studied, particularly with regard to the home dialysis program. Only 5% of the total number of ESRD facilities with home programs were included in the sample audited. That these 5% represented nearly 30% of all home patients (10 of the largest 13 home programs) is an obvious indication that the sample was heavily weighted toward the larger programs. It is doubtful that the cost experience of the high volume facilities studied was truly representative of the total population of home programs which would not have benefited from the same economies of scale.

In conclusion, as important as it is to control the rising costs associated with the ESRD Program, it surely cannot be the intent of Congress to either restrict access to this Entitlement Program or compromise the quality of care provided to these patients. It is the belief of the Ochsner Clinic that the entire ESRD Program is threatened if the proposed Regulations of February 12, 1982 are adopted as written. Should it be decided that an entire review of the methodology used to derive the proposed rates is not in order, then care needs to be given that more accurate cost data, realistic wage indexes, and adjustments for inflation are taken into consideration in the development of the final Regulations.

Thank you for the opportunity to respond to the proposed Regulations.

Sincerely,

Frank A Riddick Jr

Frank A. Riddick, Jr., M.D.
Medical Director

RJB/bc

Encl.

NURSING SALARIES VS. WAGE INDEX

PRINCIPAL CITIES	R.N. MEDIAN SALARY*	WAGE INDEX FOR URBAN AREAS
Detroit	$19,400	1.2487
Portland	$19,400	1.1212
Los Angeles	$19,200	1.3117
Chicago	$19,100	1.1979
Denver	$19,100	1.1145
Cleveland	$18,400	1.2159
Minneapolis/St. Paul	$18,300	.9899
Seattle	$18,200	1.0677
Kansas City	$18,000	.9558
Houston	$17,800	1.0810
New Orleans	$17,800	.9807
Phoenix	$17,600	1.1287
Boston	$17,500	1.1404
District of Columbia	$17,500	1.1651
Baltimore	$17,400	1.1895
New York	$17,400	1.4192
St. Louis	$17,200	1.0146
Indianapolis	$17,200	1.0684
Philadelphia	$17,100	1.2009

*Source: 1981-82 Hospital Compensation Service (John Zabka Associates)

RJB/bc
4/6/82

STANFORD UNIVERSITY HOSPITAL
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Sheldon S. King
Executive Vice President and Director
Stanford University Hospital
Associate Vice President for Medical Affairs
Stanford University

COMMITTEE ON
RECEIVED
APR 26 1982
WAYS AND MEANS

April 22, 1982

John J. Salmon
Chief Counsel
Committee on Ways and Means
1102 Longworth House Office Building
Washington, D.C. 20515

Re: Committee on Ways and Means Hearing on the Proposed Reimbursement Rates for the End Stage Renal Disease Program, April 22, 1982.

Dear Mr. Salmon:

The proposed prospective reimbursement rates will clearly inflict financial hardship on many facilities. At Stanford University Hospital, the payment rate for chronic dialysis would be reduced from $240 per dialysis to $142, which will result in a loss of approximately $400,000 per year. Therefore, implementation of the proposal would pose very difficult decisions for many institutions, including Stanford. While we constantly seek to be more efficient, our costs would have to be reduced 50% to be below the proposed rate; we do not believe this to be possible. Thus, we would be faced with the alternative of discontinuing the service or raising rates in other areas to subsidize it.

In view of the potential damage to users and providers of dialysis services, a prospective reimbursement methodology should not be introduced unless it can convincingly be shown that it does in fact provide sufficient payments for efficient institutions. The proposed methodology does not do so. As published in the February 12 Federal Register, the proposal states that "we do not have a uniformly accepted, definitive model for a dialysis session. There are no uniform standards for the numbers and qualifications of personnel, or for staff-to-patient ratios, and the dialyses service seems to vary in intensity of care depending on the patient's health status." It continues, "we do not know whether as many patients of high-cost facilities actually require as high a level of care as indicated by costs." It admits that "the first step in setting the rate is to identify the legitimate costs of economically and efficiently operated facilities. One possibility would be to identify the particular facilities that we determined, upon inspection, to be economically and efficiently operated. This option is highly subjective and imposes great administrative burdens and therefore has not been used."

Instead the proposal sets the reimbursement level at "what appears to be an adequate level to reimburse an efficient and economically operated facility." Starting with median costs as representing an approximation of the cost of an efficient operation, the methodology makes a few very minor adjustments to account for legitimate differences in expense per treatment.

No adjusting factor is included for the most important difference among providers, the complexity of case mix. An exception process is made available to account such differences, but the regulation states, "we expect that under the proposal few facilities would be able to qualify for exceptions to their payment rates. "Quotations in the paragraphs above demonstrate that the Health Care Financing Administration does not understand the reasons for cost differences among providers. Nevertheless, it has determined, in the absence of evidence, that the major reason is relative efficiency and that few facilities will be afforded relief by demonstrating a more complex case mix.

Another methodological difficulty is that no provision is made for cost inflation. As the study on which the methodology was based was conducted in March, 1980, and the cost data must have been at least one year old at that time, the target rates were set in dollars which have inflated for at least three years by 1982. In justifying the lack of an inflation factor, the proposal noted that although the current payment screen has been effective since 1974, the number of dialysis facilities has continued to grow (from 909 in 1973 to 1120 at present). Thus, it is inferred that efficiently operated facilities are not incurring suddenly rising costs. This fails to take a number of important points into account. First, although the current payment screen has not been adjusted since 1974, a relatively liberal exception mechanism has been in place which allowed *effective* payment rates to be increased with inflation. Second, the growth in dialysis facilities since 1978 has taken place almost exclusively in the independent provider sector (an increase of 70%) while the number of hospital providers has increased only 2.5%. Thus, HCFA must infer that independent facilities are the efficiently operated providers which are not incurring rising costs. One may as easily conclude that independent facilities treat a less complex and costly mix of patients and therefore thrive below the 1974 payment screen, while hospitals have encountered more difficulty in covering the costs of a more complex patient group with the current payment levels.

In summary, the proposed payment rates were developed using a methodology which is inadequate to the task. HCFA admits that it does not understand the nature of differences in cost among providers. It ignores the strong likelihood that cost differences may be explained by case mix complexity. Having failed adequately to identify payment rates which reflect effecient operations in terms of the mix of patients treated, HCFA has proposed to set a target rate which arbitrarily assumes that the median cost provider is an adequate standard for efficiency. HCFA provides an exception mechanism which has apparently been predetermined to result in little relief to providers although (again quoting the *Federal Register*) "if there were no exception process, this ... could result in dire consequences for beneficiaries if the proposed rate was insufficient to permit hospitals to continue furnishing dialysis services." Finally, in the face of economic reality, HCFA makes no provision for inflation in setting the payment rate.

The result is a payment rate which may penalize the efficient and reward the inefficient. It may well disturb service patterns and bring on serious consequences for beneficiaries. I strongly urge reconsideration of this proposal.

Sincerely,

Sheldon S. King

Sheldon S. King
Executive Vice President and Director

ESTABLISHED 1854

TOURO INFIRMARY
1401 FOUCHER STREET NEW ORLEANS, LOUISIANA 70115

April 2, 1982

Administrator
Department of Health and Human Services
Health Care Financing Administration
P. O. Box 17073
Baltimore, Maryland 21235

Re: BPP-126-P

Dear Administrator:

As the first and oldest dialysis unit in Louisiana, we have existed for over fifteen years with only minimal financial problems and have never filed for an exception; but now we find ourselves faced with a set of regulations and rates which will undermine the financial viability of the unit and may threaten its very existence. Although there are many aspects of these proposed regulations to question, I will focus my objections on the four areas that have the greatest financial impact and reflect major flaws in your development of the rates. These four areas are:

1. the inaccurate and incomplete estimation of the costs of home dialysis;
2. the failure to consider the extent of fixed costs that will be retained by a unit even if a sizeable percentage of in-center patients convert to home dialysis;
3. the refusal to allow for inflation since 1979;
4. the inaccuracy and non-applicability of the wage index used to adjust the labor component.

The major thrust of these proposed regulations is to cause a shift to less costly home dialysis. The new rates do indeed make it more profitable to maintain a home patient than an in-center patient; however, the costs to a unit for each home patient do not seem to have been fully calculated. Our proposed rate of $125.51 means that we need to achieve a 35% home patient population just to cover the decreased revenue from our in-center patients who will also be at this lower rate. Since you calculate the nationwide home patient population to be 40% at most, 35% is an extremely high percentage to achieve just to be able to continue at our present losses, which unfortunately have rapidly increased beyond the current $138 ceiling due to recent increases in the cost of supplies and labor.

There are at least two specific costs for home dialysis which I doubt you considered. Although I assume you included most all the direct supply costs, I believe those are the only costs you considered. You did not include the indirect costs medicare reimbursement rules require us to include. For example, even if we never actually see or handle the home patient's supplies, their costs must be treated like any other supplies. Therefore, all the indirect costs associated with these supplies must be added to the cost of home dialysis; this will total around $1,300 per patient per year.

I also doubt if you included the labor costs involved with a unit maintaining a home patient. Although the labor a patient himself supplies may be "free," ours certainly is not. Because problems occur unexpectedly we must keep a nurse on call and able to attend to a patient when needed. And nurses must be available for the brief monthly tubing change required of each CAPD patient. These lead to an irregular demand and thus difficulty in maintaining consistent coverage.

All these costs plus some others you excluded or undervalued led to an incorrectly low figure used to estimate home costs. You may feel that some of your low estimations are insignificant, but when our margin is already low each dollar becomes doubly costly as it not only reduces our margin from a home dialysis patient but also increases our losses from each in-center patient.

In addition to not considering all the costs for home dialysis, I feel you have overlooked the effects of all the fixed costs associated with maintaining in-center patients; these costs cannot be proportionately reduced with a simple reduction in the number of in-center patients. Historically, only through increases in the number of patients to help spread the fixed costs have we been able to live with the current $138 rate. However, if the number of in-center patients is reduced due to transfers to home dialysis as you desire, our costs per in-center patient will rapidly increase. Although some supply costs are directly related to the number of treatments almost two-thirds of the costs are basically fixed. It would be nice if all patients could be transferred to home dialysis, but by your own estimation it seems at most only 40% can; and, even if we did achieve the ideal, we could not make anywhere near a 40% reduction in labor, square feet, or equipment. In fact, we already suffered from this effect in 1981 when our in-center population remained steady and our losses more than doubled to such a figure that for the first time we will need to apply for an exception to the $138 ceiling.

My third major objection deals with your decision to ignore the effects of inflation since 1979. Your stated reason for this is that since 1978 some new units have continued to open, indicating to you that the costs still allow a unit to be financially viable. However, you apparently have not considered the type of unit they are nor whether they expected to be financially viable under the $138 ceiling or because they felt confident they would get a higher reimbursement through an exception. The vast majority of these new units were free-standing units which are often profitable to open not because the unit itself may make a profit but because the physician associated with it or actually owning it finds it personally profitable as a result of his administrative fee and the fees he receives as the patients' physician.

In general, your failure to consider inflation since 1979 seems a bit defiant in light of all the inflationary increases since then. Although inflation seems better controlled now, the past two years have already taken their toll. For example, during 1979 we paid $79 for a drum of concentrate, but today our group purchasing price is $119 - a 51% increase. Labor, a much more costly part of dialysis, has also risen considerably since 1979. General inflation alone went up 20%, but due to the severe nursing shortage in the South and due to the need to catch up on health care salaries in general, our non-nursing salaries have increased over 30% since 1979 and nurses' salaries (which make up 66% of our dialysis unit's salary expense) are 45% above what they were when you collected your data. In addition, energy, construction, and other related items have also increased tremendously since 1979; yet you seem to feel that dialysis units have been unaffected by all this and continue to operate at 1979 costs. Your refusal to allow for inflation seems an absolute denial of reality; a refusal which if maintained will result in the financial ruin of most dialysis centers and result in hardships to their patients.

The final objection I wish you to consider is the wage index you selected for adjusting the labor component. This index is inaccurate and has no direct relevance to the labor costs of a dialysis unit. The index is invalidly based on all hospital workers. Hospital labor is composed of a wide range of employees, approximately 40% of which are not involved directly in health care, and only 20% of hospital employees are nurses. However, for our dialysis unit only about 5% of the salary goes to a non-medical employee and 66% goes to our registered nurses which make up half of the staff. Although hospital-wide labor costs enter somewhat through indirect costs, this indirect effect is minimal compared to the predominance of nursing and technician salaries in a dialysis unit's labor.

Being a facility in Louisiana we find ourselves severely penalized by the nonapplicability of this wage index. Due to the makeup of the general labor supply in Louisiana, hospitals are forced to hire many minimum wage employees; in fact, around 18% of our employees are at our minimum wage level. Thus, although the hospital's total labor costs may not be higher than comparable hospitals elsewhere in the country, we hire a greater number of low wage employees, thus lowering our wage index factor unfairly. And, more telling, the same social factors that lead to a high percentage of minimum wage employees also lead to a shortage of skilled employees, and an especially severe shortage of nurses. Therefore, we are forced to pay nurses a higher salary than most other places in the country in order to recruit them from regions with less of a nursing problem and in order to entice more people to select nursing as a career. As a result of these factors, we find our dialysis unit's wage index to be unjustly low (.9807 as opposed to the average index of 1.12 for all dialysis units). We must pay our nurses well above the national average yet you place us near the bottom of the wage index.

Department of Health and Human Services
April 2, 1982

A current index of nursing salaries would be a more valid index if one for dialysis wages alone could not be developed. The inequalities of the present index are obvious because New Orleans with its .9807 index figure actually pays its nurses the same or more than almost any city in the country and certainly more than the following cities which have significantly higher index figures: Boston (1.1404), Chicago (1.1979), Dayton (1.1351), Nashville (1.0359), New York City (1.4192), Philadelphia (1.2009), Pittsburgh (1.1465), and Washington D. C. (1.1651). Although these differences may seem small, the net effect is considerable: each .1 increase in the wage index means approximately $30,000 more in revenue, which for us will mean $30,000 less lost. The inequality of this index can easily be exemplified with Pittsburgh which pays its nurses much less than we do yet has a high index of 1.1465; thus a dialysis unit similar to ours in Pittsburgh not only would have over $10,000 less expense for nursing salaries alone but would receive $50,000 more in revenue. An even more telling example is New York City where a similar unit's total nursing salary expense would be slightly less than ours yet it would receive over $130,000 more in revenue.

This inequality exists simply because you choose to use a convenient index rather than work to establish one that more equitably reflects actual labor costs. Using no labor index at all until you do develop an accurate one could not be any less equitable. If we were to receive just the average $132 per treatment our unit's net losses would be reduced by $40,000. The $132 still would not accurately reflect our labor costs in relation to other units, but it would help tremendously.

In general, I do not find the thrust of the regulations objectionable, only the procedures and data used to estimate the costs and to set the rate. Encouraging home dialysis could be more economical and possibly better for some dialysis patients. As a unit that has always done some home dialysis (we still have one of the nation's first patients to go on home dialysis) and as a unit that encourages its patients to use CAPD or CCPD, we have over the years lost reimbursement as well as suffered actual net losses because of our interest in home dialysis. Therefore, financial incentives for home dialysis would normally be welcome; however, the rate as proposed will only bring us even greater financial losses. Your failure to consider all the costs of home dialysis and your fialure to understand the problems of fixed costs with an existing unit are in themselves serious flaws in your determination of a rate. But your denial of any inflationary factor is a refusal to face the financial and economic realities not only of a dialysis unit but of the nation as a whole, and your use of an invalid and non-applicable wage index simply because it is convenient is a sign of laziness and indifference to the real financial plight of dialysis units. The use of the proposed wage index rather than one more validly related to dialysis wages or even just nursing salaries will cost our unit at least $60,000 in revenue, which in our case is a $60,000 increase in the net loss of the unit. That combined with the lost revenue from your failure to allow for inflation and other factors will turn our unit from one that has suffered only marginal losses in the past to one that will experience excessive and severe losses, losses that will eventually if not immediately necessitate the Board of Managers to review the very existence of this unit.

Sincerely,

Earl F. Luetzelschwab
Coordinator, Therapeutic Services

EFL/dbl

[illegible] SUBCOMMITTEE

William M. Turner, M.D., P.A.
416 EAST CALHOUN STREET
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Stark
Rosty/ John
for

April 19, 1982

Mr. John Salmon, Chief Council
House Ways and Means Committee
1102 Longworth House Office Building
Washington, D. C. 20515

Dear Mr. Salmon:

I am writing you at the suggestion of Mrs. Grace Pearson, a member of Congressman Butler Derricks's staff.

I am writing in reference to the upcoming committee hearings on End Stage Renal Disease Reimbursement proposed Regulation proposed in the Federal Register on February 12, 1982.

I have spent many hours writing many letters about these regulations. I would like to boil them down to save a lot of time and discussion here to my very basic objections, and then make some suggestions.

Under objections are the following:

1. I object to the amount of the cut. I believe that the amount of the proposed cut is excessive, and will kill dialysis across the country if these regulations are proposed. The death will be slow and agonizing, but will come nevertheless. Under this objection I include an objection to the lack of a real mechanism for making any profit at all, in view of the fact that inability to make any profit at all will eliminate any incentive for development of new clinics. Although it may be the silent wish of Congress to eliminate all of the dialysis clinics, eliminating such clinics will also eliminate the large number of patients depending upon them for their existence. Although some patients may be able to be treated at home certainly all cannot, and the patients who cannot will be eliminated. Further, all future patients who cannot be run at home will not be offered the same chance of treatments once the clinics are full. These reimbursement proposals have a number of areas that directly block the incentive for offering new patients to dialysis, at least by developing new clinics, and I fear that the need has not yet been met with the present clinics. Your children and mine will not have the same opportunity of dialysis should the present proposed regulations go into effect. Private enterprise has demonstrated a willingness and a capability to operate in an efficient and economic manner, and the reason large profits were made were because of the level of Congressionally approved reimbursement initially. I agree that the amount originally approved when the program was started was too high for that date, but do not feel like we can look backward at that number and decide what the present number should be. I believe that a careful scrutiny of the audit methods used by an independent facility would indicate that the audit methods were not properly converted to a statistical analysis of the need

and the regulations do not reflect an accurate picture of the needed amount of reimbursement for dialysis to stay afloat.

2. I object to the regional wage index. Money that is forwarded to the Federal Government in form of taxation should be returned to the areas as needed on a dollar for dollar basis. It seems improper to me that South Carolina should be required to take an 83¢ on the dollar return for it's Medicare when New York receives a $1.20 on the dollar return. Heretofore such has not existed. I disagree that this economic maneuver should be done also because I feel also that it continues to place the burden on South Carolina to be more economical than other areas where the reimbursement may be higher. I would challenge that if a clinic is in existence and functioning at the present reimbursement rate there is no excuse for raising its reimbursement higher other than to compensate it for changes in inflation. Therefore, the area wage index that is in excess of one is a conceptual falacy.

I do not see any attempt to apply the area wage index to income tax collected from various rural areas, but perhaps if labor is really cheaper in those areas the Internal Revenue Service and all of the people who live in these areas might consider such a maneuver. However, at the present time for each dollar I earn I pay fixed percent of income tax. This is determined by the Internal Revenue Service and it doesn't take into account where I earn this dollar or how hard I had to work at it. I might even suggest that if I have to work at an 83% wage then in effect I have had to work harder for my dollar to send it to Washington than someone who has gotten a higher compensation for the same amount of work. Therefore, my taxation has been in excess of theirs already. To return less than a dollar for an equal service is ludicrous and improper.

3. I object to the failure to identify a precise time frame when updates in reimbursement will occur and a formular whereby these updates in reimbursement will occur. Failure to do so does not allow a clinic to take into account such factors as inflation and its operating procedures. The many months necessary to apply for an exemption of the rules would not allow a clinic to continue to exist in these financial hard times where interest rates are in the realm of 20%, and money would have to be borrowed to cover actual cost while Congress or HCFA considered the exception process. Consider then if you would the fact that a clinic operating on an absolutely tight "ends meet" type of budget with absolutely no profit (this is the way we would have to operate under the new regulations) was suddenly faced with a 10% rise in cost of supplies. With no profit and no margin at all, he would be forced to go to the bankers to buy enough supplie to keep going. Then there would be a 20% actual cost to the dialysis clinic in interest rates. There would be no margin for this built in the books, so there would be no way to absorb this. Further, the banker would look with less than favor on lending money where the ability to pay it back would depend upon the potential approval of reimbursement under an exception process of the rules already in effect. The inability to buy supplies because I could not borrow the money would result in inability to dialyze and treat my patients and this would subsequently result in their death.

4. I am enclosing a copy of a talk I received from another physician who attended the Renal Physicians Association meeting mentioned in the title page. I strongly object to the philosophy mentioned in this talk. I particularly refer to paragraphs on page 11 of this talk that presume to give public policy makers any say at all in who gets what kind of treatment. I believe this philosophy must be fairly typical of that that prevails in the Health Care and Finance Administration if such philosophy

was mentioned openly at this meeting of this sort. The paragraphs I refer to are those that mention public policy making with regard to deciding whether or not people who have many more years to live or cannot be returned to a near normal productivity should be treated. I hope that you will carefully scrutinize this particular aspect of the talk. It is to me personally quite nauseating, and reflects a very serious problem in the basic concept of the practice of medicine.

Now the suggestions:

1. I suggest that the cuts be made back to $128.00 screen, but that it be made across the board, eliminating the area wage index.

2. I suggest that you require HCFA to spell out precisely how often the reimbursement will be reviewed, and automatically updated according to the various economic indexes that apply to it. I further suggest here that the precise formulation of these updating procedures be made public and that the time frame for these updates be quite realistic and no further than a year apart, and preferably every six months.

3. All further regulations that have to do with ESRD reimbursement should not be allowed to increase the cost of operating the dialysis clinic without passing the amount of that increase on to the reimbursement carrier. Thus, a new stack of paperwork generated by some obscure regulation could not be required at the expense of the clinic. This would make the rulemakers more attentive to the plight of the clinics with regard to cost containment.

4. There should be some incentive offered to the clinics to maintain a satisfactory profit margin. Thus, after the above mentioned cuts have been made clinics would not be further penalized by this type of maneuver again should efficiencies become apparent that can allow them to exist with a profit margin which would preclude financial diaster should inflation overtake the clinics.

Comment: When you are running a $4.00-$6.00 per treatment profit margin and the cuts called for are $24.00 per treatment about all you can hope to do is make ends meet by rather disastrous adjustments in your operating procedures. Having made these ends meet you are then faced with operating on a shoestring. Should inflation catch up with that tiny margin, the result would be a disaster.

Such a disaster would result in the death of many people across the country. I find it objectionable to pretend that there is anything that has been offered so far that will allow clinics to exist in a realistic fashion should these regulations be passed as proposed and the clinic find itself in such financial straights that it could not exist further. I believe the onslaught of request for exemptions under the regulations will be so great that HCFA will not be able to effectively handle them and people will die because these regulations are being proposed in an unrealistic manner and an unrealistic amount and in an unrealistic time frame. If you believe that 40% of the 68,000 people on hemodialysis in 1981 could be trained for home dialysis in the time period allowed for making these adjustments you are quite wrong. The proposed regulations have as their basic incentive a cost containment by the mechanism of encouraging people to perform home hemodialysis and peritoneal dialysis as an outpatient. It is not possible to accomplish this. Since we are talking about life or death treatment here, I think it is time someone quit comparing this type of treatment to such things as heart transplants and such and realize that we are already treating these people and they are already on machines and already being preserved and they are going to die if their treatment programs are stopped because of the death of the dialysis clinic. The proposed regulations will ultimately kill dialysis patients by killing dialysis clinics. Clinics cannot survive on the reimbursement that is proposed in most areas where there is a cut below the $128.00 mark.

I respectfully submit that you consider these facts carefully before acting. To query the committee that wrote these regulations about their comments is like asking the fox to guard the henhouse. You will not in my opinion get an accurate or true view. Few of you have ever been to a dialysis clinic, and few of you are aware of the plight of the dialysis clinic as such, only the plight of the Government. I submit further that many cuts could be made that would be much more effective in cost containment for the Federal Government, and certainly would result in no disaster to anyone.

I wish these comments to be made part of the record and the testimony on this issue to be held by the House Ways and Means Committee.

I regret that I did not have an opportunity to attend this meeting. I did not find out about the date of the meeting or the final mechanism for being invited to testify until today. A phone call revealed that the committee was already scheduled for a full slate of testimonies so I cannot deliver this in person, but would beg you to consider these facts that I submit here.

Most sincerely,

William M. Turner, M.D.

WMT:lgm

[Attachment.—Appendix C]

REMARKS BY DR. JAMES F. DONOVAN, ASSOCIATE ADMINISTRATOR FOR MANAGEMENT AND SUPPORT SERVICES, HEALTH CARE FINANCING ADMINISTRATION AT THE ASSOCIATION OF RENAL PHYSICIANS, MARCH 19, 1982, KEY LARGO, FLA.

(NOTE.—This text is the basis of Associate Administrator Donovan's oral remarks. It should be used with the understanding that some material may be added or omitted during presentation.)

I want to thank you for inviting me to your conference. I am here not just as a spokesman for the Health Care Financing Administration, but as a fellow physician as well. We belong to a profession dedicated to saving life—and in your capacity as renal physicians, you have done much of that.

Government has been a partner in this life-saving venture from the very outset. The arteriovenous shunt developed in 1960 gave renal physicians access to the circulatory system of a person suffering from cronic renal failure. For the first time renal dialysis was practical for large numbers of people with end stage renal disease.

The pioneering research that made this possible was heavily subsidized by the Federal Government. Still, by 1968 only 15 percent of the people with end stage renal disease could get this expensive treatment. Physicians at that time had two choices: treat patients on a first-come, first-served basis, or select those most likely to survive and lead productive lives. Neither approach could be entirely satisfactory to most physicians.

In effect, the lack of facilities and the high cost of treatment made renal dialysis a rationed service. Then, in October of 1972, Congress extended Medicare coverage to persons with ESRD and suddenly a door was opened wide.

On many accounts, the ESRD program has succeeded beyond reckoning: it has extended life for tens of thousands; access to services has been good; and the cost to patients has been modest indeed.

POLICY PROBLEMS

But viewed from a policy standpoint, the 1972 ESRD breakthrough must be seen in far less congratulatory terms:

From the outset, it has lacked a consistent and sound regulatory framework, in part because of ambiguities and subsequent changes in the enabling legislation;

The data needed to determine actual treatment costs and track emerging trends has not been forthcoming;

The program has postponed, but not resolved, a continuing debate over who should receive expensive life-saving treatments in a time of scarce and competing medical resources;

Finally, we created a health service at taxpayer expense that is available to all in need but lacking the vital criteria needed to control its use.

The inevitable consequence of all this is a program whose costs have grown alarmingly: In 1974, 18,000 patients were receiving treatments at a cost to Medicare of $229 million. By 1981, there were more than 68,000 patients being treated at a cost totalling a billion and a half dollars.

ESRD patients today represent less than a quarter of one percent of all the people covered under Medicare Part A, yet they account for over 9 percent of its expenditures. Much of this outlay is understandable—treatment is, after all, expensive. But part of it is due simply to policy shortcomings that have gone unremedied, until recently.

These policies prevent hospitals that operate renal dialysis facilities from keeping any revenues beyond Medicare's allowable cost and this robs them of incentive to manage efficiently. The impact of this policy is clearly evident in our Agency's analysis of 1981 audit data. It shows that the median cost of hospital-based dialysis is 25 percent higher than in free-standing facilities, which are reimbursed on a more generous "reasonable charge" basis. But even though free-standing facilities have a lower median cost, no savings to Medicare results since our policy permits them to pocket the difference between their actual cost and what we pay.

It is small wonder that free-standing facilities have grown in number so rapidly—from 68 in 1973 to 466 last year. Nowhere near that rate of expansion has occurred among hospital facilities. There were 536 of them in 1973 and 654 last year. These Government policies have created perverse incentives that are costing the American taxpayer money but do nothing to fulfill the Nation's commitment to patients suffering chronic renal failure. And Government policy has failed as well to encourage less expensive dialysis in patients' homes. Home dialysis costs about $97 per treatment. Over a Year's time, that comes to a savings of around $5,000 compared to facility dialysis. When suitable, it is just as safe and just as effective as dialyzing in a facility.

Our figures show that up to 40 percent of all end Stage Renal Disease patients could be dialyzed at home—but in fact, just 17 percent are.

Meanwhile, the National Government—your partner—is in financial trouble. This year, the national debt crossed the trillion dollar mark. The interest alone on that debt is now a hundred billion dollars. That's enough to pay for all of our Federal health, education and nutrition programs combined. The President is trying to fight inflation and the high interest rates that heavy government borrowing create by reducing Federal expenditures. That effort is crucial to the economic future of the nation, and it is crucial to the people who have been thrown out of work because of our economic trouble.

In view of these circumstances, it is only natural that the fast-rising cost of health care has become a focus of the Administration's effort to contain Federal spending. The figures tell an alarming story: between 1965 and 1980, outlays for health care grew at a rate one-third higher than the annual growth in GNP—12.5 percent; health outlays as a percentage of GNP keep growing—from 6 percent in 1965 to 9.4 percent in 1980; and outlays for health care are now well over $200 billion and fast approaching 10 percent of GNP.

There are reasons for these trends, not the least of which is medical progress and the easy financial access to the expensive modern care that today's financing structure provides. Programs like Medicare and Medicaid have been a powerful factor in providing that access. In 1965, when Medicare and Medicaid were enacted, Government was footing 25 percent of the nation's total health care bill. By 1980, it was paying for 40 percent.

Government has become a major financer of health care. With that role comes the obligation to the taxpayer to ensure that what it pays goes for needed health care—not waste or inefficiency. The growing cost of the ESRD program must be seen within this context, together with our recent proposals in the Federal Register to reform ESRD reimbursement policies.

REFORMING POLICY

Our goal in reforming these policies is not to make life tougher for you as renal physicians. Nor is it to reduce the ESRD caseload. It is to make this, and other programs as well, lean and efficient so as to reduce the alarming pace of Federal expenditures and speed economic recovery. The good that results will redound to everyone in this room.

Achieving a more cost-effective ESRD program will require a minimum of sacrifice and a maximum of every-day cost consciousness. We in Government have done our part by proposing regulations that will give you a dollar-and-cents incentive to do that, and I'll be discussing that now.

PLAYING CATCH UP BALL WITH CONGRESS

Reforming ESRD is a project long overdue. That work has been interrupted by successive change in the law. In 1980, for example, the Health Care Financing Administration conducted a round of audits to estimate the actual cost of providing dialysis services. This was done to carry out the mandates of the Amendments Congress enacted for the end state renal disease program in 1978. But before HCFA could finish this work, Congress acted again in 1981. This time, they passed an amendment requiring us to set up payment rates that differentiate between hospital and free-standing facilities—as well as to provide, through a payment rate structure, an incentive to dialyze more patients in their own home. The goals were to be achieved by paying the same reimbursement rate for dialysis, whether performed at a patient's home or in a facility. And since home dialysis costs less, this should give providers of care a clear economic incentive to dialyze patients at home whenever suitable.

Last year's amendments also expressed a preference for developing separate rates for hospitals and free-standing facilities. We developed a formula for establishing these separate rates and if you like I will be happy to discuss it with you later. As you know, these proposals are spelled out in the regulations we proposed on February 12th that we have asked you to comment upon—and we will welcome your comments. Our proposed regulations also set forth details of an exceptions process that would consider requests for higher payments to facilities that can justify them. A case in point might be, for example, a pediatric dialysis unit that has a high ratio of staff to patients.

PHYSICIAN REIMBURSEMENT

In the end, physicians are the key to efficient and cost-effective treatment, since it is they who order and supervise those treatments. It is in recognition of this that we have also proposed a revision in the way physicians are reimbursed. Our purpose is to encourage more efficiency in providing dialysis services and to provide an incentive to dialyze patients at home. Current regulations specify two methods for paying you. One, the Initial Method, reimburses the facility and includes the cost of your services in supervising patient care. The Alternative Method pays you a higher monthly fee for dialyzing in a facility than in the patient's home. This, of course, discourages home dialysis because it pays you less for dialyzing patients at home.

We propose to pay you a single monthly fee, regardless of where you order the dialysis to be performed. This will eliminate an economic incentive to dialyze in facilities. The fee we propose is based on a formula that takes into account the proportion of patients now being dialyzed at home. In addition to changing the current perverse incentives, the new reimbursement policies we propose will be far simpler to administer. This will ease the burden on Medicare's intermediaries and carriers, giving them more time to perform audits and consider rate exception requests.

We have also developed new cost reporting forms for hospitals and for free-standing facilities. These segregate costs by the mode of treatment so the data they yield will help intermediaries to perform more accurate cost reviews when they consider requests for rate exceptions.

REORGANIZATION OF ESRD IN HCFA

As you know, the Administration of ESRD was changed last summer when a discrete office for this purpose was dismantled. I know you dislike this arrangement. With a single ESRD office, you had a contact point for resolving questions. Our reason for this change is based on the changing character of the ESRD program. It was once a developing program that demanded a special focus, but it has not matured. As a mature program, ESRD demands the specialized expertise that only the functional arms of our agency can provide. We think that his realignment will improve the internal decisionmaking process and impose policy implementation.

From our standpoint, the reorganization is better. From yours, I full well acknowledge that it may be worse—you have lost a handy contact point that you were accustomed to having. I understand that concern and I propose this to you: Within reasonable bounds, I will offer to serve [illegible] your contact for any major issues that arise concerning ESRD matters. Routine questions that come up can be fielded by the others in our agency.

LONG RANGE CONSIDERATIONS

My purpose today has been to explain the "whys" of our proposed new reimbursement policies for covering End Stage Renal Disease. I have not touched on a larger issue of public policymaking that must one day be faced. It centers around the question: Should people with little chance of living many more years or of being returned to a near-normal functioning life be treated? This decision has traditionally been left to the physician, and as you well know it is indeed a lonely one. But that same question must one day be raised in a public policy context. The policy question must be phrased in a broader context—do we have enough resources as a society to pay fully for this and other emerging medical technologies?

How, we must someday ask, can Government justify paying for dialysis treatments, but not for heart transplants, coronary bypass surgery, or other expensive life-saving procedures that may be developed? This issue lays bare the sobering fact that tens of thousands of patients with different chronic and catastrophic conditions are in fact competing for a share of the Nation's limited resources.

Last year, the New England Journal of Medicine published a suvey of 2,500 ESRD patients in 18 dialysis centers. It revealed that 53 percent of them were over age 50, 45 percent were unemployed and nearly one-quarter were unable to care for themselves without assistance. Findings like these pose large and serious questions for the future—questions that I am not about to suggest answers to, but which nonetheless need to be considered by the renal dialysis community and all within medicine.

These questions are no less important to the American people at large, whether in the role of patient or taxpayer. They take on a particular urgency in the context of our current efforts to develop a coherent national health policy while we grapple at the same time with the need to reduce Federal outlays and get our economy on track again.

Some have suggested that the government establish a committee to draw up guidlines for determining who shall have renal dialysis.

This is a suggestion with Orwellian overtones and whether government should even take it up is itself a complex and sensitive question. I would suggest to you only, as renal physicians, that your judgment and experience will be needed as dialogues of this nature emerge in the years ahead—as emerge they surely will.

SUMMARY

Meanwhile, I want to conclude my remarks by pointing out that the reimbursement policies we are proposing are designed to ease the kind of economic pressures that will one day lead us to a solemn confrontation with issues of this kind. The system we are proposing is designed to benefit every interest group in volved: The Federal Government will benefit by realizing a lower rate of expenditures for ESRD; those who operate facilities will benefit by having the chance to realize income from more efficient operations and wider use of home dialysis; and finally, patients will benefit because more of them will have a greater chance to dialyze at home whenever that is appropriate.

I know you'll agree with the view that patients must remain our uppermost concern as we shape renal dialysis policies for the future. We want to keep on serving those who need this life-saving care and the best way to ensure that tomorrow is by making that care as cost effective as we can today. I suggest to you that it is in your interest as well as your Government to accept the measures we have proposed.

We have an opportunity now to develop a more coherent ESRD policy than was ever before possible. Let's seize it while time still gives us the chance to exercise options that the future might foreclose. That is the challenge I bring before you today. For thousands of people with chronic renal failure, the stake is too high to demand anything less than your most throughtful response to that challenge. For my part, I am confident that you will respond to that challenge because no one realizes better than you that our real agenda for this discussion is human life, now and in the future. Thank you.

APPENDIX D

These Regulations are illegitimate because: The Data is inconsistent, of variable age, incomplete; the Methodology is undocumented, unexplained, arbitrary and unfair; the Abruptness of implementation is impraticable and damaging; and the Review of rates is not annually or done by a specified formula.

Further: The Physician reimbursement is exceptional discrimination against the nephrologist based on minimal and atypical data. It defines a complex multi-dimensional service by one scale and denigrates the service and the doctor. The "Dual Rate" produced is a charade. The Deletion of 100 percent purchase of home dialysis equipment is damaging, weakening the home hemodialysis option. The Exception criteria will not protect access to backup facilities in hospitals. Some are subject to state rules which raise costs.

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